IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LYNN OXENBERG and RONALD LEWIS *Plaintiffs,* v. ALEX AZAR II, in his official capacity as the Secretary of the Department of Health and Human Services. *Defendant.*	Case No. 2:20-cv-00738-CMR

DECLARATION OF JAMES C. PISTORINO IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

I, James C. Pistorino, Esq., declare as follows:

I am an attorney with the law firm Parrish Law Offices. I represent the Plaintiffs in the above-captioned action. I submit this Affidavit in support of Plaintiffs' Motion for Summary Judgment.

Attached hereto as Exhibit A is a true and correct copy of a decision issued by Administrative Law Judge Thomas Strafuss on June 3, 3019 in ALJ Appeal No. 1-845246824.

The Secretary did not appeal Judge Strafuss' decision and it has become final.

Attached hereto as Exhibit B is a true and correct copy of a decision issued by Administrative Law Judge Carolyn Cohn-Morros on September 5, 2019 in ALJ Appeal No. 1-8651098761.

The Secretary did not appeal Judge Cohn-Morros' decision and it has become final.

Attached hereto as Exhibit C is a true and correct copy of a decision issued by Administrative Law Judge Carolyn Cohn-Morros on October 24, 2019 in ALJ Appeal No. 3-8686737644.

The Secretary did not appeal Judge Cohn-Morros' decision and it has become final.

Attached hereto as Exhibit D is a true and correct copy of a decision issued by Administrative Law Judge Bruce MacDougall on September 5, 2019 in ALJ Appeal No. 1-8393258352.

Attached hereto as Exhibit E is a true and correct copy of a requests for escalation related to Judge MacDougall's decision.

Attached hereto as Exhibit F is a true and correct copy of a decision issued by Administrative Law Judge Gerald Hynum on October 24, 2019 in ALJ Appeal No 3-8693279102.

The Secretary did not appeal Judge Hynum's decision and it has become final.

Attached hereto as Exhibit G is a true and correct copy of a decision issued by Administrative Law Judge Pamela Levine on May 30, 2019 in ALJ Appeal No. 1-8411344383.

Attached hereto as Exhibit H is a true and correct copy of a requests for escalation related to Judge Levine's decision.

I declare under penalty of perjury under the laws of the United States of America that the foregoing statements are true and correct.

Dated: March 30, 2020

/s/ *James C. Pistorino*
James C. Pistorino, Esq.
PARRISH LAW OFFICES
788 Washington Road
Pittsburgh, PA 15228
(412) 561-6250
james@dparrishlaw.com
Attorney for Plaintiffs

EXHIBIT A

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
Kansas City, MO 64106
816-599-3300 (Main)
816-599-3300 (ALJ Strafuss Team)
816-527-0115 (Fax)
844-566-6258 (Toll Free)

Date: June 3, 2019

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 1-8452468241

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

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- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

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Medicare Appeals Council, MS 6127
Cohen Building Room G-644
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Washington, D.C. 20201

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(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

L. OXENBERG

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

NOVOCURE INC.
195 Commerce Way
Portsmouth, NH 03801

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	**L. Oxenberg**	ALJ Appeal No.:	**1-8452468241**
Enrollee:	**L. Oxenberg**	Medicare Part:	**B**
HICN:	******6114A**	Before:	**Thomas C. Strafuss** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant, L. Oxenberg.

PROCEDURAL HISTORY

Appellant submitted a claim to Noridian Healthcare Solutions, the Medicare Administrative Contractor ("Contractor") with jurisdiction, for electrical stimulation treatment (E0766, tumor treatment field therapy) for dates of service of July 5, 2018; August 5, 2018; September 5, 2018; and October 5, 2018. (Exh. 1, pp. 1-12) The claim was denied initially and at the redetermination level. (*Id.*) C2C Solutions, Inc., a Qualified Independent Contractor ("QIC"), upheld the Contractor's determination in a decision issued March 19, 2019. (*Id.*)

On April 10, 2019, the Office of Medicare Hearings and Appeals ("OMHA") received Appellant's timely request for a hearing before an Administrative Law Judge ("ALJ"). The requested hearing was conducted on May 28, 2019. Debra Parrish, attorney, appeared on behalf of the Appellant and Julie Miles, R.N., appeared telephonically on behalf of Novocure. Noridian submitted a position paper. The case file was admitted into the record.

ISSUE

Whether all Medicare coverage requirements have been met warranting payment under Title XVIII of the Social Security Act ("the Act"), and, if coverage requirements have not been met, whether the limitation of liability provisions in § 1879 are applicable.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Appellant, a 68 year old female, has been diagnosed glioblastoma multiforme. (Exh. 2, pp. 1-64; Exh. 3, pp. 1-8) Appellant is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device (Optune) for brain cancer treatment provided through Novocure. (*Id.*)

2. On December 6, 2018, Noridian Healthcare Solutions denied Appellant's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment. (Exh. 1, pp. 26-30) Noridian Healthcare Solution's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)

3. On March 19, 2019, the QIC examined Appellant's claim and affirmed Noridian Healthcare Solution's denial of coverage. (Exh. 1, pp. 1-12)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See* Social Security Act (the Act), Title XVIII, § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. § 405.1000(g) and § 405.1038(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* § 1814(a)(1), § 1815(b), and § 1833(e) of the Act; *see also* 42 C.F.R. §424.5(a)(6), § 405.1018, § 405.1028, and § 405.1030.

II. Principles of Law

A. Statutes and Regulations

The Social Security Act of 1965 ("The Act") implements a social insurance program for qualifying beneficiaries. The Act also delegates the authority to create Medicare Policy to the Secretary of the U.S. Department of Health and Human Services ("DHHS"). This policy comes in the form of standards issued in the Code of Federal Regulations ("C.F.R"). In addition to the Act and the policies in the C.F.R., the Medicare Program also is governed by the Federal Register ("F.R."), National Coverage Determinations, and the Centers for Medicare & Medicaid Services ("CMS") rulings. Though they do not have the force of law the previous sources carry, Administrative Law Judges ("ALJ") give substantial deference to Medicare transmittals and Medicare Manuals, and Local Coverage Determinations ("LCD"). LCDs are created by a Medicare contractor and they detail Medicare coverage for certain items or services.

According to Section 1862(a)(1) of the Act, "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Furthermore, according to § 1833(e) of the Act, "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Section 1832(a) of the Act states that under Medicare part B, an individual is entitled to Medicare coverage for "medical health and other health services." According to § 1861(s), of the Act, "medical health and other services" includes "durable medical equipment" ("DME"), which meets the following criteria as detailed under 42 C.F.R. § 414.202:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

42 C.F.R. § 410.38 articulates the following scope and conditions for DME: "Medicare part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution used as a home."

The Centers for Medicare & Medicaid Services ("CMS") has developed the Healthcare Common Procedure Coding System ("HCPCS") to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). Medicare reimbursement is contingent upon a supplier using HCPCS codes when filing claims for items or services provided.

B. Policy and Guidance

Though not binding on ALJs administering Medicare appeals, manuals and rulings issued by the Centers for Medicare and Medicaid Services ("CMS") are used in implementing the Medicare program. ALJs must give the manuals and rulings substantial deference. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the ALJ must explain the reasons why the policy was not followed. 42 C.F.R. § 405.1062(b).

Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states:

> Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

Appellant, a 68 year old female, has been diagnosed glioblastoma multiforme. (Exh. 2, pp. 1-64; Exh. 3, pp. 1-8) Appellant is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device (Optune) for brain cancer treatment provided through Novocure. (*Id.*)

On December 6, 2018, Noridian Healthcare Solutions denied Appellant's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment. (Exh. 1, pp. 26-30) Noridian Healthcare Solution's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)

On March 19, 2019, the QIC examined Appellant's claim and affirmed Noridian Healthcare Solution's denial of coverage. (Exh. 1, pp. 1-12)

The Medicare Contractors CGS Administrators, LLC, and Noridian Healthcare Solutions, currently have a LCD L3482. As previously noted, that LCD simply states that tumor treating field therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD as to why tumor treatment field therapy should not be compensated by Medicare. The only substance is a reference section entitled "Sources of Information and Basis for Decision." That section lists several citations which presumably support the summary conclusion that tumor treating field therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are generally required to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The undersigned ALJ deviates from the current LCD for the reasons discussed herein.

The FDA issued a premarket approval of Optune (a tumor treatment field therapy device) consistent with the prescribed use by the treating physician on November 2, 2015. (Exh. 1, pp. 1744-1752)[1] FDA approval generally means the treatment has been deemed safe and effective. The most recent phase three clinical trial submitted by Novocure,[2] published in December 2015, shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma, and increases the overall odds of survival. (Exh. 1, pp. 1733-1743) This study was also updated with new data and analysis showing continued positive results in articles dated December 19, 2017, and February 1, 2018. (Exh. 1, pp. 1713-1732) Further, the 2018 National Comprehensive Cancer Network ("NCCN") Guidelines allow for alternating use of electric field therapy with Temozolomide when treating glioblastoma. (Exh. 2, pp. 1709-1712.)

Additionally, there is a proposed LCD currently in the comment period that would cover tumor treatment field therapy, and the Appellant in this case would fit within the very specific and limited parameters set out in the proposed LCD. (Exh. 2, pp. 1-64; Exh. 4, 24-38; Hearing testimony.) Specifically, there must be: a newly diagnosed and confirmed glioblastoma multiforme; the patient must have received initial treatment with maximal debulking surgery followed by chemotherapy and radiation; initiate tumor treatment field therapy within 7 weeks from last dose of concomitant chemotherapy or radiation; receive care for glioblastoma multiforme at a National Cancer Institute-designated comprehensive cancer center, designated cancer center, or designated cancer research network facility; no evidence of cancer progression; maintain a Karnofsky Performance Score of at least 70 or greater; and use tumor treatment field

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[1] The FDA had issued an earlier approval for Optune (NOVOTFF -100A System) on May 6, 2011. The approval was limited to the recurrence of glioblastoma multiform after receiving chemotherapy. The current FDA approval includes newly diagnosed GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (*Id.*)

[2] Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. *See* http://jama.jamanetwork.com/article.aspx?articleie=2475463

therapy for at least 18 hours per day. Continued coverage beyond first 3 months requires a face-to-face clinical reevaluation with objective evidence of adherence to treatment. (*Id.*)

Here, the Appellant underwent surgery for glioblastoma multiforme on December 13, 2017, and she was on Temodar (Temozolomide) and radiation until intolerance developed. The brain cancer was Grade IV per the World Health Organization designation. The evidence shows a Karnofsky Performance Score of 90 % or greater with tumor treatment field therapy use around 22 hours per day. There has been no evidence of tumor progression. Initiation of tumor treatment field therapy occurred in a timely manner. The Appellant has been receiving treatment at an approved facility. Finally, the evidence shows continued follow up with a face-to-face clinical reevaluation with objective evidence of compliance. (Exh. 2, pp. 1-64 and hearing testimony).

In summation, the Appellant suffers from glioblastoma, which is the very condition/cancer this device is designed to treat. When all taken together the documentation supports the conclusion that the Optune device is safe and effective and no longer experimental or investigational. Therefore, while the ALJ does not reject the current LCD, the ALJ declines to give it controlling weight. The ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Part B and thus Medicare coverage must be approved.

CONCLUSIONS OF LAW

Based on the evidence of record, the undersigned ALJ finds that Medicare Part B coverage does exist for electrical stimulation for cancer treatment (E0766, tumor treatment field therapy) provided to the Beneficiary for dates of service of July 5, 2018; August 5, 2018; September 5, 2018; and October 5, 2018.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

SO ORDERED,

Dated: JUN 0 3 2019

Thomas C. Strafuss
U.S. Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8452468241**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Thomas Strafuss** Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents	1-1908
2	Medical Records/Evidence Received by CMS Contractors	1-64
3	Request for ALJ Hearing	1-8
4	OMHA Proceedings	1-65

Dated: 06/03/19

EXHIBIT B

Department of Health and Human Services
Office of the Secretary

RECEIVED SEP 09 2019

19-310

OFFICE OF MEDICARE HEARINGS AND APPEALS

Irvine Field Office
19 Technology Drive, Suite 200
Irvine, CA 92618
949-788-8000 (Main)
949-788-3611 (ALJ Cohn-Morros Team)
949-788-3660 (Fax)
866-495-7414 (Toll Free)

Date: SEP - 5 2019

L. OXENBERG
8302 OLD YORK RD APT A23
ELKINS PARK, PA 19027-1531

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 1-8651098761

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(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

DME MAC Noridian Healthcare Solutions, LLC
P.O. BOX 6780
FARGO, ND 58108-6780

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8651098761**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Carolyn Cohn-Morros** Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the administrative record and at the hearing, a **FULLY FAVORABLE** decision is entered for **L. OXENBERG** (the "Appellant" or the "Beneficiary").

Procedural History

The appeal is before the undersigned Administrative Law Judge ("ALJ") following prior adverse determinations made by the Medicare Administrative Contractor ("MAC") and by C2C Innovative Solutions, Inc., the Qualified Independent Contractor ("QIC"), which denied the Appellant's claim for coverage for tumor treatment field therapy ("TTFT" or "TTF") (E0766) provided on November 5, 2018, December 5, 2018, and January 5, 2018 (the "dates of service") (Exh. 1).

Following receipt of the QIC's unfavorable decision, the Appellant filed a Request for hearing before an ALJ, which was received by OMHA on June 24, 2019 (Exh. 3, p. 1). The Appellant's Request for an ALJ Hearing satisfies the request for hearing requirement specified in Title 42 Code of Federal Regulations (C.F.R) Section 405.1002(a)(1) because the Appellant's Request for Hearing was filed within 60 days of the QIC's reconsideration decisions (Exhs. 1 and 3). The Appellant waived the right to receive notice of hearing at least 20 calendar days before the date of the hearing (Exh. 4).

On August 15, 2019, a telephonic hearing was held in this matter in Irvine, California (Hearing CD). Ms. Debra Parrish, Esq. appeared and argued on behalf of the Appellant. Mr. Timothy Parks, R.N., the Clinical Appeals Specialist of NovoCure, also appeared and testified on behalf of the Appellant. The MAC and QIC did not appear at the scheduled hearing. No other parties appeared at the hearing. All of the Exhibits were admitted into evidence without objection.

Issues

1. Whether the tumor treatment field therapy (TTFT) device, specifically the electrical stimulation center treatment (E0766), provided to the Appellant on the dates of service is covered by Medicare.

2. If not, whether the waiver of liability provisions contained in Sections 1879 of the Social Security Act (the "Act") apply, and to whom.

Findings of Fact

1. The Appellant was diagnosed with glioblastoma (i.e. a fast growing brain tumor) in December 2017 and she received surgery, chemotherapy, and radiation (Exh. 2, pp. 1-30). She completed chemotherapy radiation in February 2018 (*Id.* at 4).

2. She was prescribed TTFT to treat the Appellant's cancerous brain tumor and by April 27, 2018, she reported that she was using it 22 hours a day (Exh. 2, p. 22). The Appellant indicated that she had no scalp issues and her neuropathic pain was better (*Id.*).

3. On July 6, 2018, the magnetic resonance imaging (MRI) scan of her brain showed a slowly increasing size of neoplasm in her right lateral temporal lobe (Exh. 2, p. 19). By July 27, 2018, the MRI scan showed no overt evidence of progressive neoplasm (*Id.* at 17). Her doctor noted that the Appellant was doing well with the TTFT and recommended continuing treatment (*Id.*)

4. On September 14, 2018, the Appellant reported that she continued to do well with the TTFT and was "very active" (Exh. 2, p. 2). Her doctor noted that the Appellant incurred a liver injury with another treatment called Temodar, therefore, they proceeded with TTFT as the only maintenance therapy (*Id.*)

5. Glioblastoma multiforme (GBM) is the most prevalent malignant brain tumor in adults. Survival at initial presentation is approximately 10 months, and upon recurrence, approximately six month, even with aggressive chemotherapy. Because it is extremely rare for glioblastoma to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy (Exh. 4).

6. Optune, formerly known as NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or Tumor Treating Fields to the brain. The device consists of an electric field generator that is connected to four insulate transducer arrays. The arrays are place on the patient's scalp and deliver the Tumor Treating Fields Therapy (or TTFT) to the patient's glioblastoma. The fields slow the replication of the cancer cells or stop their growth all together. Optune has been approved by the United States (U.S.) Food and Drug Administration (FDA) to deliver TTFT therapy (Exh. 4).

7. The Appellant submitted a Review Article entitled, *"NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: randomized phase III trial of a novel treatment modality,"* in support of its position (Exh. 2, pp. 1400-1410). Thirty (30)

physicians from various universities and hospitals across the globe, including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTF therapy for patients diagnosed with glioblastoma. As expected, conventional chemotherapy toxicity caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTF therapy. Furthermore, multiple animal experiments showed the "enhanced affect [when] TTF is combined with chemotherapy." Because of this successful animal trial, the U.S. and Europe have approved this device for the treatment of glioblastoma (*Id.*).

8. The Appellant submitted a randomized clinical trial entitled, "*Maintenance Therapy with Tumor-Treating Fields plus Temozolomide vs. Temozolomide Alone for Glioblastoma*" in support of its position. (Exh. 2, pp. 1322-1331). The clinical trial included 695 patients with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. This clinical trial found that by adding TTFT with Temozolomide chemotherapy, it "*significantly* prolonged progressive-free and overall survival" (*Id.*).

9. The Appellant submitted an extensive clinical oncology report entitled, "*Clinical Cancer Advances 2018: Annual Report on Progress against Cancer from the American Society of Clinical Oncology*," from the Journal of Clinical Oncology, which discussed cancer advances in 2018. This article addressed glioblastoma patients treated with TTFT. Clinical research found that the "risk of death" was reduced by 37% for patients using the TTFT device as compared to patients using chemotherapy alone. Additionally, TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 2, pp. 217-233).

10. The Appellant submitted a case report entitled, "*Long-term survival of patients suffering from glioblastoma multiforme treated with Tumor-Treating Fields*," from the World Journal of Surgical Oncology, which discussed case studies of four patients treated with TTFT. In this case report, two patients with glioblastoma multiforme (GBM) were treated with TTFT and two patients with recurrence glioblastoma multiforme (RGBM) were treated with TTFT. Consequently, after 7 years, the two patients with GBM and the two patients with RGBM were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence." (Exh. 2, pp. 1314-1321).

11. The Appellant submitted numerous fully favorable decisions by ALJs addressing TTF therapy. This Exhibit was 1303 pages and it included both Part C and Part B appeals. (Exh. 1, pp. 39-1256).

12. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields) cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields.

Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or *reversing* this disease."[1]

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Section 1869(b)(1)(A) of the Act.

In implementing this statutory directive, the Secretary has delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *See* 74 Fed. Reg. 65296 (December 9, 2009). A hearing before an ALJ is available only if the remaining amount in controversy meets the jurisdictional amount. 42 Code of Federal Regulations (C.F.R) § 422.600(b). A request for hearing is timely if filed within sixty days after receipt of the reconsideration decision. 42 C.F.R. § 422.602(b).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

C. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

An ALJ is bound by statutes, regulations, national coverage determinations ("NCD"), and Medicare Rulings. (42 C.F.R. §§ 405.4060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination ("LCD") or Medicare program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a

[1] https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

particular case. (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. (42 C.F.R. § 405.1062(b).)

Section 1862(a)(1)(A) of the Social Security Act ("Act") provides that notwithstanding any other provisions of title XVIII of the Act, items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from coverage.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies *not binding* on the ALJ or attorney adjudicator and Council provides:

> (a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.
>
> (b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.
>
> (c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

> (a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.
>
> (b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.
>
> (c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R §426.310 LCD and NCD reviews and individual claim appeals provide:

> (a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

> (b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 provides who may challenge an LCD or NCD.

> (a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.
>
> (b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

Future LCD L3482, which is effective on September 1, 2019 – Tumor Treatment Field Therapy (TTFT) provides in part:

> Coverage Indications, Limitations, and/or Medical Necessity
> . . .
> The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.
>
> In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:
>
> For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
>
> **Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.** (Emphasis added).
> . . .

HCPCS Codes

. . .

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

. . .

Policy Article A52711- Tumor Treatment Field Therapy (TTFT) provides in part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.

Separate billing of supplies and/or accessories will be denied as unbundling.
Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES
Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2016 provides that alternating electric field therapy for glioblastoma and is a category 2B recommendation.

The related Policy Article **A52711** states in pertinent part:

> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
>
> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
>
> Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.
>
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>
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>
> This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.
>
> Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

ANALYSIS

The issue on appeal is whether the Appellant is entitled to coverage for the TTFT device (HCPCS code E0766) provided on the dates of service under Medicare Part B.

Medicare makes payment on items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body

member." *See* § 1862(a)(1) of the Act. All Medicare claims for payment must be supported by sufficient information and documentation. *See* § 1833(e) of the Act.

The Appellant's attorney representative, Ms. Debra Parrish, stated that the Appellant was diagnosed with a glioblastoma in December of 2017. The Appellant received surgery, chemotherapy and radiation. Ms. Parrish stated that the Appellant was prescribed the Optune device to deliver TTFT treatment to her glioblastoma. Ms. Parrish stated that the Contractor denied the claims stating that the device was not reasonable and necessary. She explained that the QIC found that the studies do not document the effectiveness of the device, that the effectiveness of the device was not quantified for this Appellant, and that the LCD requirements were not met. Ms. Parrish argued that the studies show that the device is indeed effective; so much so that one trial was suspended due to its effectiveness. She argued that the evidence on the effectiveness of the device at issue is overwhelming. Ms. Parrish went onto state that the device received a level 1 approval, which is a unanimous agreement that the device is effective. Ms. Parrish argued that the other LCDs that apply to TTFT have been retired in 2015. Without an LCD, Medicare coverage is determined by peer-reviewed literature, a consensus of experts, and whether or not the relevant medical community has adopted the technology. Ms. Parrish asserted that the retired LCDs do not apply to patients who have recently been diagnosed with glioblastoma. Also, Ms. Parrish argued that the LCD is inconsistent with current medical literature and it is not substantiated by the medical community (Hearing CD).

In her position brief, Ms. Parish submitted the Local Coverage Determination Tumor Treatment Field Therapy (TTFT) (L34823) (Exh. 4). The future LCD L34823, which is effective on September 1, 2019, provides that TTFT (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme when the following criteria are met:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery, followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy; and,
4. The beneficiary is receiving care for GBM at a National Cancer Institute-designated Cancer Center, National Cancer Institute-designated Comprehensive Cancer Center, or National Cancer Institute-designated Cancer Research Network facility; and,
5. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
6. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
7. The beneficiary will use TTFT for at least 18 hours/day.

At the hearing, Ms. Parrish noted that the Appellant meets all the criteria in the future LCD. (Hearing CD).

Mr. Timothy Parks, the Clinical Appeals Specialist of NovoCure, appeared and testified on behalf of the Appellant. Mr. Parks testified that the Appellant suffered from a newly diagnosed glioblastoma. On December 2017, an MRI scan showed the tumor and the Appellant underwent chemotherapy. By February 2018, she completed the chemotherapy treatment and started Optune with chemo temozolomide on April 15, 2018. Mr. Parks testified that the Appellant has since had

a stable MRI on July 12, 2018. He asserted that the Appellant was using the TTFT 90 percent of the time and her KPS was now 90 after the Optune treatment (Hearing CD).

The testimony provided by Mr. Parks and the argument provided by Ms. Parrish were trustworthy, credible, persuasive, and supported by the record.

After carefully considering the evidence in the record as well as the arguments and testimony presented at the hearing, the ALJ finds that the TTFT device was medically reasonable and necessary for the Appellant and Medicare coverage shall be allowed.

First, TTFT has been approved by the Food and Drug Administration (FDA)[2] since April 2011. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease."[3] The FDA asserts that cancer growth is slowed and can be reversed after using this device.

Second, the Beneficiary meets the criteria for future LCD L34823, which is effective on September 1, 2019. Until such time as the future LCD is effective, there is no LCD in effect and if the retired LCDs (L34734, L34665, L34730, and L34738) were in in effect, the ALJ would decline to follow them for a multitude of reasons. The retired LCDs stated that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." Nevertheless, the QIC based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. The retired LCDs categorically deny that *any* TTFT treatment is reasonable and necessary under *any* circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. The retired LCDs are noticeably outdated and ignore medically relevant data from the most prestigious medical institutions in the world including medical opinions, research articles, peer-review studies, university research, clinical oncology reports, etc., and it ignores the medical findings of the FDA in the last eight years. The current scientific data and research supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant. TTFT is not experimental or investigational but has been approved by the FDA. Furthermore, the sparse nature of any medical reasoning in the retired LCDs provide additional reasons not to follow it here, where the medical evidence, testimony, and argument so

[2]The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, such as the Appellant, with newly-diagnosed GBM. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm.

[3] https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

overwhelmingly support the Appellant's case. Regardless of the guidance provided by the retired LCDs, a departure from the guidelines set forth in these LCDs is required based upon the Appellant's serious condition, the great benefits realized by the Appellant after using this device, and the vast medical findings and research in the last decade. Furthermore, federal regulations *permit* ALJs to decline to follow a local coverage policy. 42 C.F.R. Sec. 405.1062.

Third, the evidence supports the need for this device pursuant to Section 1862(a)(1) of the Social Security Act. Sufficient information was provided to corroborate the Appellant's contentions pursuant to Section 1833(e) of the Social Security Act. *See* 42 C.F.R. § 424.5(a)(6). The Appellant was suffering from a deadly malignant brain tumor and needed the best treatment which could be afforded to her. The Appellant suffered from glioblastoma, which is an aggressive form of brain cancer. She was provided extensive treatment since her diagnosis in December 2017. The Appellant underwent surgery, chemotherapy, radiation, and eventually she was prescribed TTF therapy. The Appellant, on the advice of her treating doctor, seeks coverage for the treatment services furnished by NovoCure. The Optune treatment or NovoTTF-100A System was highly recommended by her doctor. This therapy uses alternating electrical fields to interfere with the rapid growth and division of cancer cells. The Appellant provided over 1,000 pages of medical literature in support of its position. The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for this Appellant.

For example, thirty physicians from universities and hospitals across the globe including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, etc., performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT. They found that conventional chemotherapy treatment caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple experiments suggest the enhanced affect when TTF is combined with chemotherapy (Exh. 2, pp. 1400-1410).

The Appellant also submitted a randomized clinical trial in which 695 patients were treated with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results were very remarkable. The clinical trial concluded that adding TTFT with Temozolomide chemotherapy "*significantly* prolonged progressive-free and overall survival" (Exh. 2, pp. 1322-1331).

The Appellant submitted a clinical oncology report, which discussed cancer advances in 2018. This report discussed glioblastoma patients treated with TTFT and it found that the "risk of death" was reduced by 37% for patients using the TTFT device compared to those who used only chemotherapy. TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 2, pp. 217-243).

The Appellant submitted a case report, which discussed case studies on four specific patients treated with TTFT, two patients with glioblastoma multiforme (GBM) and two patients with recurrence glioblastoma multiforme (RGBM). After seven years these four patients were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence" (Exh. 2, pp. 1314-1321). Thus, after weighing all the evidence, the medical reasonableness and necessity for using such a device to treat the Appellant's condition was clearly warranted. Even though the treatment was very expensive, it is comparable to using expensive chemotherapy drugs, which are not as effective as TTFT.

Fourth, the QIC has provided no medical evidence to cast any doubt on the effectiveness of the TTFT treatment, especially as applied to treating this Appellant. In fact, there is no evidence on the contrary in the record. Furthermore, the QIC and MAC failed to appear and to contest the evidence submitted in the record and presented by the Appellant's representative and witness.

Lastly, the Appellant substantially meets the criteria provided in the future LCD L34823, which is effective on September 1, 2019. Even though the proposed LCD is yet to be effective, coverage in this appeal is consistent with Medicare's policy movement towards coverage of TTFT for glioblastoma. Therefore, for all these reasons, the TTFT device was medically reasonable and necessary, is currently the best treatment for the Appellant's condition and shall be covered pursuant to the provisions of Section 1862(a)(1) of the Social Security Act.

As this decision is fully favorable, the limitation of liability issue is moot and need not be discussed.

CONCLUSIONS OF LAW

1. The Appellant is entitled to coverage for the TTFT (E0766) provided on the dates of service. This device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by the Appellant, and Section 1862(a)(1) of the Social Security Act. Medicare payment shall be allowed on the TTFT device.

2. The limitation of liability under Section 1879 of the Social Security Act does not apply, as the issue is moot.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: SEP - 5 2019

Carolyn Cohn-Morros
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8651098761**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Carolyn Cohn-Morros** **Administrative Law Judge**

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents (pages 39 - 1632 in separate box)	1-38 39 - 1632
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Dated: 9/05/19

[1] Some materials in the exhibited record are dual sided. References to the second side include a notation of (reverse). For example, "Ex. 1, p. 1 (reverse)." The second side of a dual sided page is not included in the page count for the page number range.

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, and any other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 9.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment of representative if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

NOTICE OF NONDISCRIMINATION

The Office of Medicare Hearings and Appeals (OMHA) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. OMHA does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

OMHA:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - TTY calls that are initiated by the caller through a public relay service
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)

- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact (866) 207-4466.

If you believe that OMHA has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al (866) 207-4466.

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 (866) 207-4466.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa (866) 207-4466.

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số (866) 207-4466.

ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le (866) 207-4466.

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم (866) 207-4466

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. (866) 207-4466 번으로 전화해 주십시오.

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: (866) 207-4466.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните (866) 207-4466.

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele (866) 207-4466.

ध्यान दें: यदि आप हिंदी बोलते हैं तो आपके लिए मुफ्त में भाषा सहायता सेवाएं उपलब्ध हैं। (866) 207-4466 पर कॉल करें।

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para (866) 207-4466.

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero (866) 207-4466.

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer (866) 207-4466.

خبردار: اگر آپ اردو بولتے ہیں، تو آپ کو زبان کی مدد کی خدمات مفت میں دستیاب ہیں۔ کال کریں (866) 207-4466

If you need large print, please call 1-866-207-4466

EXHIBIT C

Department of Health and Human Services
Office of the Secretary

19-486

OFFICE OF MEDICARE HEARINGS AND APPEALS

Irvine Field Office
19 Technology Drive
Suite 200
Irvine, CA 92618-2364
(866) 495-7414
(949) 788-3611 (Direct)
(949) 788-3660 (Fax)
(866) 495-7414 (Toll Free)

October 24, 2019

PARRISH LAW OFFICES
ATTN: DEBRA PARRISH
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 3-8686737644

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.
##PAGEBREAK##
How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this

notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

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Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod.**

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new.** You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.
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Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.
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CC: L. Oxenberg

C2C Innovative Solutions, Inc.

Enclosures: Exhibit List

DAB-101 Request for Review of Hearing Decision/Dismissal Order

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**3-8686737644**
Beneficiary:	**L. OXENBERG**	Medicare Part:	B
Medicare No.:	*******6114A**	Before:	**Carolyn Cohn-Morros** Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the administrative record and at the hearing, a **FULLY FAVORABLE** decision is entered for **L. OXENBERG** (the "Appellant" or the "Beneficiary").

PROCEDURAL HISTORY

The appeal is before the undersigned Administrative Law Judge ("ALJ") following prior adverse determinations made by the Medicare Administrative Contractor ("MAC") and by C2C Innovative Solutions, Inc., the Qualified Independent Contractor ("QIC"), which denied the Appellant's claim for coverage for tumor treatment field therapy ("TTFT" or "TTF") (E0766) provided on February 5, 2019, March 5, 2019, April 5, 2019, and May 5, 2019 (the "dates of service") (Exh. 1, p. 4).

The Appellant filed a timely request for hearing before an Administrative Law Judge ("ALJ") and the amount in controversy satisfies the jurisdictional requirement for this appeal.

The Appellant requested in writing that the Administrative Law Judge ("ALJ") decide the case without a hearing. The undersigned ALJ hereby grants the Appellant's request and issues this decision pursuant to 42 C.F.R. § 405.1038(b). The entire file is admitted into the record without objection.

ISSUES

1. Whether the tumor treatment field therapy (TTFT) device, specifically the electrical stimulation center treatment (E0766), provided to the Appellant on the dates of service is covered by Medicare.

2. If not, whether the waiver of liability provisions contained in Sections 1879 of the Social Security Act (the "Act") apply, and to whom.

APPLICABLE LAW AND POLICY

I. ALJ Review Authority

A. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

B. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

An ALJ is bound by statutes, regulations, national coverage determinations ("NCD"), and Medicare Rulings. (42 C.F.R. §§ 405.4060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination ("LCD") or Medicare program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. (42 C.F.R. § 405.1062(b).)

Section 1862(a)(1)(A) of the Social Security Act ("Act") provides that notwithstanding any other provisions of title XVIII of the Act, items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from coverage.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies *not binding* on the ALJ or attorney adjudicator and Council provides:

> (a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.
>
> (b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.
>
> (c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB

may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

(a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R §426.310 LCD and NCD reviews and individual claim appeals provide:

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 provides who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

LCD L3482, which was effective on September 1, 2019 – Tumor Treatment Field Therapy (TTFT) provides in part:

> Coverage Indications, Limitations, and/or Medical Necessity
> . . .
> The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.
>
> In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:
>
> For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
>
> **Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.** (Emphasis added).
> . . .
>
> HCPCS Codes
> . . .
> E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE
> . . .

Policy Article A52711- Tumor Treatment Field Therapy (TTFT) provides in part:

> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
>
> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
>
> Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.
>
> Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.
>
> Separate billing of supplies and/or accessories will be denied as unbundling.

Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES
Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2016 provides that alternating electric field therapy for glioblastoma and is a category 2B recommendation.

The related Policy Article A52711 states in pertinent part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

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Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

FINDINGS OF FACT AND ANALYSIS

The issue on appeal is whether the Appellant is entitled to coverage for the TTFT device (HCPCS code E0766) provided on the dates of service under Medicare Part B.

Medicare makes payment on items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See* § 1862(a)(1) of the Act. All Medicare claims for payment must be supported by sufficient information and documentation. *See* § 1833(e) of the Act.

Here, the Appellant was diagnosed with glioblastoma (i.e. a fast growing brain tumor) in December 2017 and she received surgery, chemotherapy, and radiation (Exh. 5, pp. 46-54; Exh. 7, pp. 16-93). She completed chemotherapy radiation in February 2018 (*Id.*). She was prescribed TTFT to treat the Appellant's cancerous brain tumor and by April 27, 2018, she reported that she was using it 22 hours a day (*Id.*). The Appellant indicated that she had no scalp issues and her neuropathic pain was better (*Id.*). On July 6, 2018, the magnetic resonance imaging (MRI) scan of her brain showed a slowly increasing size of neoplasm in her right lateral temporal lobe (*Id.*). By July 27, 2018, the MRI scan showed no overt evidence of progressive neoplasm (*Id.*). Her doctor noted that the Appellant was doing well with the TTFT and recommended continuing treatment (*Id.*). On September 14, 2018, the Appellant reported that she continued to do well with the TTFT and was "very active" (*Id.*). Her doctor noted that the Appellant incurred a liver injury with another treatment called Temodar, therefore, they proceeded with TTFT as the only maintenance therapy (*Id.*). On February 19, 2019, the Appellant's TTFT prescription was renewed (*Id.* at 58). On April 5, 2019, the Appellant underwent an MRI scan, which revealed there was "continued stability and no evidence of tumor progression" (*Id.* at 39).

The Appellant's attorney representative, Ms. Debra Parrish, stated in the Request for Reconsideration, that the Appellant was prescribed the Optune device to deliver TTFT treatment to her glioblastoma (Exh. 7, p. 4). Ms. Parrish stated that the Contractor denied the claims stating that the device was not reasonable and necessary (*Id.*). She explained that the QIC found that the studies do not document the effectiveness of the device, that the effectiveness of the device was not quantified for this Appellant, and that the LCD requirements were not met (*Id.*). Ms. Parrish argued that the studies show that the device is indeed effective; so much so that one trial was suspended due to its effectiveness (*Id.*). She argued that the evidence on the effectiveness of the device at issue is overwhelming. Ms. Parrish went onto state that the device received a level 1 approval, which is a unanimous agreement that the device is effective (*Id.*). Ms. Parrish argued that the other LCDs that apply to TTFT have been retired in 2015 (*Id.*). Without an LCD, Medicare coverage is determined by peer-reviewed literature, a consensus of experts, and whether or not the relevant medical community has adopted the technology (*Id.*).

Ms. Parrish asserted that the retired LCDs do not apply to patients who have recently been diagnosed with glioblastoma (*Id.*). Also, Ms. Parrish argued that the LCD is inconsistent with current medical literature and it is not substantiated by the medical community (*Id.*).

In the Request for Reconsideration, Ms. Parish argued that LCD L34823, which was effective on September 1, 2019, provides that TTFT (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme when the following criteria are met:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy; and,
4. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
5. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
6. The beneficiary will use TTFT for at least 18 hours/day.

After carefully considering the evidence in the record, the ALJ finds that the TTFT device was medically reasonable and necessary for the Appellant and Medicare coverage shall be allowed.

First, TTFT has been approved by the Food and Drug Administration (FDA)[1] since April 2011. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease."[2] The FDA asserts that cancer growth is slowed and can be reversed after using this device.

Second, the Beneficiary meets the criteria for LCD L34823, which was effective on September 1, 2019. Before LCD L34823 was effective, there was no LCD in effect and if the retired LCDs (L34734, L34665, L34730, and L34738) were in in effect, the ALJ would decline to follow them for a multitude of reasons. The retired LCDs stated that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." Nevertheless, the QIC based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. The retired LCDs categorically deny that *any* TTFT treatment is reasonable and necessary under *any*

1The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, such as the Appellant, with newly-diagnosed GBM. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm.

2 https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. The retired LCDs are noticeably outdated and ignore medically relevant data from the most prestigious medical institutions in the world including medical opinions, research articles, peer-review studies, university research, clinical oncology reports, etc., and it ignores the medical findings of the FDA in the last eight years. The current scientific data and research supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant. TTFT is not experimental or investigational but has been approved by the FDA. Furthermore, the sparse nature of any medical reasoning in the retired LCDs provide additional reasons not to follow it here, where the medical evidence, testimony, and argument so overwhelmingly support the Appellant's case. Regardless of the guidance provided by the retired LCDs, a departure from the guidelines set forth in these LCDs is required based upon the Appellant's serious condition, the great benefits realized by the Appellant after using this device, and the vast medical findings and research in the last decade. Furthermore, federal regulations *permit* ALJs to decline to follow a local coverage policy. 42 C.F.R. Sec. 405.1062.

Third, the evidence supports the need for this device pursuant to Section 1862(a)(1) of the Social Security Act. Sufficient information was provided to corroborate the Appellant's contentions pursuant to Section 1833(e) of the Social Security Act. *See* 42 C.F.R. § 424.5(a)(6). The Appellant was suffering from a deadly malignant brain tumor and needed the best treatment which could be afforded to her. The Appellant suffered from glioblastoma, which is an aggressive form of brain cancer. She was provided extensive treatment since her diagnosis in December 2017. The Appellant underwent surgery, chemotherapy, radiation, and eventually she was prescribed TTF therapy. The Appellant, on the advice of her treating doctor, seeks coverage for the treatment services furnished by NovoCure. The Optune treatment or NovoTTF-100A System was highly recommended by her doctor. This therapy uses alternating electrical fields to interfere with the rapid growth and division of cancer cells. The Appellant provided over 1,000 pages of medical literature in support of its position. The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for this Appellant.

For example, the Appellant submitted a Review Article entitled, "*Novo TTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: randomized phase III trial of a novel treatment modality,*" in support of its position. Thirty physicians from universities and hospitals across the globe including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, etc., performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT. They found that conventional chemotherapy treatment caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple experiments suggest the enhanced affect when TTF is combined with chemotherapy (Exh. 2, pp. 1390-1400).

The Appellant also submitted a randomized clinical trial entitled "*Maintenance Therapy with Tumor-Treating Fields plus Temozolomide vs. Temozolomide Alone for Glioblastoma,*" in which 695 patients were treated with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results were very remarkable. The clinical trial concluded that adding TTFT with Temozolomide chemotherapy "*significantly* prolonged progressive-free and overall survival" (Exh. 2, pp. 1313-1321).

The Appellant submitted an extensive clinical oncology report entitled, "*Clinical Cancer Advances 2018: Annual Report on Progress against Cancer from the American Society of Clinical Oncology,*" from the Journal of Clinical Oncology, which discussed cancer advances in 2018. This report discussed glioblastoma patients treated with TTFT and it found that the "risk of death" was reduced by 37% for patients using the TTFT device compared to those who used

only chemotherapy. TTFT was also found to double the 5-year survival rate from 5% to 13% (Exh. 2, pp. 207-233).

The Appellant submitted a case report entitled, "*Long-term survival of patients suffering from glioblastoma multiforme treated with Tumor-Treating Fields,*" from the World Journal of Surgical Oncology, which discussed case studies of four patients treated with TTFT. In this case report, two patients with glioblastoma multiforme (GBM) and two patients with recurrence glioblastoma multiforme (RGBM). After seven years these four patients were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence" (Exh. 2, pp. 1306-1311). Thus, after weighing all the evidence, the medical reasonableness and necessity for using such a device to treat the Appellant's condition was clearly warranted. Even though the treatment was very expensive, it is comparable to using expensive chemotherapy drugs, which are not as effective as TTFT.

Fourth, the QIC has provided no medical evidence to cast any doubt on the effectiveness of the TTFT treatment, especially as applied to treating this Appellant. In fact, there is no evidence on the contrary in the record. Furthermore, the QIC and MAC failed to appear and to contest the evidence submitted in the record and presented by the Appellant's representative and witness.

Lastly, the Appellant substantially meets the criteria provided in LCD L34823, which was effective on September 1, 2019. The coverage in this appeal is consistent with Medicare's policy movement towards coverage of TTFT for glioblastoma. Therefore, for all these reasons, the TTFT device was medically reasonable and necessary, is currently the best treatment for the Appellant's condition and shall be covered pursuant to the provisions of Section 1862(a)(1) of the Social Security Act.

As this decision is fully favorable, the limitation of liability issue is moot and need not be discussed.

CONCLUSIONS OF LAW

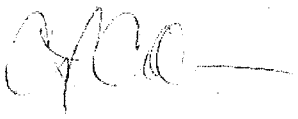
1. The Appellant is entitled to coverage for the TTFT (E0766) provided on the dates of service. This device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by the Appellant, and Section 1862(a)(1) of the Social Security Act. Medicare payment shall be allowed on the TTFT device.

2. The limitation of liability under Section 1879 of the Social Security Act does not apply, as the issue is moot.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE.** The undersigned ALJ directs The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED



Carolyn Cohn-Morros
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of: **L. OXENBERG**	OMHA Appeal No.: **3-8686737644**
Beneficiary: **L. OXENBERG**	Medicare Part: **B**
Medicare No.: *******6114A**	Before: **Carolyn Cohn-Morros** Administrative Law Judge

Index of the Administrative Record and Exhibit List

Exhibit Record	**Administrative File Reference**	
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Medical & Related: Medical Records	File 5	21 : 256
Guidance: LCD: LCD Guidance/ Complaint	File 2	1 : 3402
Procedural - CMS Levels: QIC Acknowledgment Letter	File 1	1 : 4
Procedural - CMS Levels: Reconsideration	File 3	1 : 16
Procedural - CMS Levels: Request for Redetermination: w/attached	File 5	1 : 256
Procedural - CMS Levels: Request for Reconsideration: w/attached	File 7	4 : 107
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Procedural - OMHA Level: Response to Notice of Hrg: D. Parrish	File 12	1 : 3
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Non-Exhibit Record	**Administrative File Reference**	
	File Name	Page Range
Records not considered: Duplicate evidence	File 11	1 : 4
Records not considered: Duplicate evidence: response to Noridian	File 15	1 : 45
Records not considered: Duplicate evidence	File 17	1 : 4
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Records not considered: Duplicate evidence	File 4	1	: 15
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Records not considered: Duplicate evidence: response to Noridian	File 9	1	: 45

EXHIBIT D

Department of Health and Human Services
Office of the Secretary

19-127

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
Kansas City, MO 64106
816-599-3300 (Main)
816-321-7269 (ALJ MacDougall Team)
816-527-0051 (Fax)
844-566-6258 (Toll Free)

Date: September 5, 2019

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 1-8393258352

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that

you are requesting an expedited review within 60 calendar days after receipt of this notice of decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

C2C Innovative Solutions, Inc.
DME QIC Appeals—ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	**L. Oxenberg**	OMHA Appeal No.:	**1-8393258352**
Beneficiary:	**L. Oxenberg**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Bruce MacDougall** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, I enter an **UNFAVORABLE** decision for L. Oxenberg ("Appellant").

PROCEDURAL HISTORY

The Appellant submitted claims to Medicare for charges related to an Optune® TTFT (tumor treating field therapy) electrical stimulation device (HCPCS code E0766) provided to the Beneficiary on monthly rental periods beginning April 5, 2018; May 5, 2018; and June 5, 2018. Noridian Healthcare Solutions, the Medicare Administrative Contractor ("Contractor") with jurisdiction, denied the claim initially and on redetermination. The Appellant requested reconsideration from C2C Innovative Solutions, Inc., a Qualified Independent Contractor (QIC), and on March 12, 2019, the QIC issued an unfavorable reconsideration. (Exh. 1, p. 1). On March 25, 2019, the Office of Medicare Hearings and Appeals (OMHA) received Beneficiary's request for a hearing before an Administrative Law Judge ("ALJ"). (Exh. 3, p. 6).

On July 10, 2019, ALJ Bruce MacDougall held a hearing by telephone conference. Debra Parrish represented the Appellant, with Tim Parks also appearing and providing testimony. All exhibits were admitted into the record.

ISSUE

Whether all Medicare coverage requirements have been met warranting payment under Title XVIII of the Social Security Act for the TTFT provided to the Beneficiary for dates of service beginning on April 5, 2018; May 5, 2018; and June 5, 2018? If the coverage requirements were not met, are the limitations on liability provisions of section 1879 of the Act applicable?

FINDINGS OF FACT

The record shows that the Beneficiary has been diagnosed with glioblastoma multiforme. The record also shows that the Beneficiary's physician recommended that she receive TTFT. The current device was delivered to the Beneficiary on April 5, 2018; May 5, 2018; and June 5, 2018, and had been used continuously. At the hearing the Beneficiary's legal counsel, Debra Parrish, noted that both the medical community and medical literature supports widespread adoption of TTFT. Ms. Parrish urged the ALJ to deviate from the current LCD (LCD L34823) that does not permit coverage of TTFT, noting recent developments in the process of amending the current LCD. *See generally*, (Exh. 1; Hearing Testimony).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services ("HHS"), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act ("Act") § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decision of the Secretary, unless the individual/organization appeals to the Medicare Appeals Council. *Id.*

A request for hearing is timely if it is received by OMHA within 60 days after the party received the reconsideration decision, unless the individual/organization establishes good cause to extend the time to file. 42 C.F.R. §§ 405.1002(a)(1) and 405.1014(c). The Appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration, unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the party's favor at any prior level of review. 42 C.F.R. § 405.1032(a). The ALJ assigned to hear this matter may give notice to the parties of any other issue will be addressed at the hearing. 42 C.F.R. § 405.1032(b). The ALJ may also issue a decision on the record at the request of a party and there are no other parties who wish to appear. 42 C.F.R. § 405.1038(b). The ALJ may also issue a decision on the record on his/her own initiative if the evidence in the record supports a fully favorable finding. 42 C.F.R. § 405.1038(a).

A party may not offer new evidence for the first time at the ALJ level of review unless good cause exists. 42 C.F.R. § 405.1018(c). The party must submit a statement explaining why the evidence not previously submitted. *Id.* The ALJ will examine the statement and evidence to establish whether good cause was established. 42 C.F.R. § 405.1028(a). This restriction is not applicable to unrepresented beneficiaries or oral testimony given during the course of a hearing. 42 C.F.R. § 405.1018(d).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue and makes a decision based on the evidence, without regard to the findings made by the lower levels on the claim. 42 C.F.R. § 405.1000(d). The Appellant bears the burden of proving each element of the Medicare claim. Act §§ 1814(a)(1), 1815(b), and 1833(e); *see also* 42 C.F.R. §§ 405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

D. *Statutes & Regulations*

The statutory authority for the Medicare program is found in Title XVIII of the Act. 42 U.S.C. § 1395 *et. seq.* The Medicare program is divided in multiple parts. Medicare Part B is a voluntary insurance program that provides medical insurance benefits to "aged and disabled individuals" for services not covered under Medicare Part A (or Part D). Act § 1831. The individual must elect to enroll in the program. *Id.* The program is financed through contributions appropriated by the Federal Government in addition to premium payments. *Id.* The Secretary of the Department of Health and Human Services has the authority to promulgate regulations which define or clarify the provisions of the Act. 42 C.F.R. § 410 *et seq.*

In accordance with section 1862(a)(1)(A) of the Act, Medicare may not make a payment under Part A or Part B for anything which is not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Under section 1833(e) of the Act, the provider is responsible for providing sufficient documentation to support that payment is due and the services were medically necessary and provided as billed. *See also* 42 C.F.R. § 424.5(a)(6).

In the event the services are found to be "not medically reasonable and necessary," or "custodial in nature," under § 1862(a)(1) or (9) of the Act, § 1879 of the Act provides for limitation on liability for Medicare payments. If the beneficiary had no knowledge that the services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. § 411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under § 1879 of the Act. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. 42 C.F.R. § 411.406.

E. Policy and Guidance

CMS (Centers for Medicare and Medicaid Services) Rulings and national coverage decisions ("NCDs") are binding on ALJs. 42 C.F.R. §§ 405.1060, 405.1063(b). CMS and its contractors have also issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals or local coverage determinations ("LCDs"). The applicable provisions in the LCDs and Medicare manuals are entitled to substantial deference to the extent they are consistent with the Act, regulations, and rulings; deviation from them must be explained. 42 C.F.R. § 405.1062. All relevant LCDs and Medicare manuals are hereby given substantial deference. 42 C.F.R. § 405.1062.

In determinations involving original Medicare coverage and payment issue, ALJs are not bound by LCDs, but must give substantial deference to these policies when such policies are applicable. 42 C.F.R. § 405.1062(a). If an ALJ does not follow a policy in a particular case, the ALJ must explain why in the decision. 42 C.F.R. § 405.1062(b). An ALJ may not set aside or review the validity of an LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD, or any part of an LMRP that constitutes an LCD, in accordance with 42 C.F.R. Part 426: *Review of National Coverage Determinations and Local Coverage Determinations*. 42 C.F.R. § 405.1062(c).

Applicable in this case is CGS Administrators, LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (January 2017) (LCD L34823). Also applicable is CGS Administrators, LLC, Local Coverage Article A52711: Tumor Treatment Field Therapy (TTFT) (January 2017) (Article A52711).

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions. For the items addressed LCD L34823, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity:

> "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." LCD L34823.

Payment rules set forth in Local Coverage Article A52711 state that tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit pursuant to section 1861(s)(6) of the Social Security Act. In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. Article A52711.

In addition to the "reasonable and necessary" criteria contained LCD L34823, there are other payment rules that must also be met prior to Medicare reimbursement. These payment rules are described in CGS Administrators, LLC Local Coverage Article A55426: Standard Documentation Requirements for All Claims Submitted to DME MACs (V50) (Article A55426) (August 2018); the Supplier's Manual; and additional bulletin articles and other publications related to this LCD located on the DME MAC web sites.

The Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM), ch. 13 § 13.5.1, and the Medicare Benefit Policy Manual (CMS Pub. 100-02) (MBPM), ch. 15 § 110, provide guidance for determining whether a device is reasonable and necessary. These manuals suggest that a device is not reasonable and necessary if it is:

a) Not safe and effective – that is, if the device has not been "proven safe and effective based on authoritative evidence" or is not "generally accepted in the medical community as safe and effective for the condition for which it is used."
b) Experimental or investigational;
c) Not appropriate for the individual beneficiary's needs; or,
d) Substantially more costly than a medically appropriate and realistically feasible alternative pattern of care.

Medicare also instructs contractors as to the type of evidence to be used in making these technical determinations. Such decisions should be based on either published authoritative evidence such as definitive randomized clinical trials or general acceptance by the medical community, with the caveat that acceptance by individual health care providers and limited case studies distributed by sponsors with financial interest in the outcome are not sufficient evidence of general acceptance by the medical community. MPIM § 13.7.1.

ANALYSIS

The ALJ conducted a *de novo* review of the evidence to determine whether the Appellant established that the services provided to the Beneficiary on the dates of service here at issue met coverage and payment criteria under Medicare regulations and Title XVIII of the Social Security Act.

The Beneficiary is seeking Medicare coverage of TTFT treatments (E0766) provided on dates of service April 5, 2018; May 5, 2018; and June 5, 2018 to treat glioblastoma multiforme.

The QIC denied the appeal on the basis that the LCD categorically denies coverage for tumor treatment field therapy. (Exh. 1, pp. 1-7). The Appellant contends that Medicare should cover the contested services on the basis that the treatments are reasonable and medically necessary for the Beneficiary and because the statements made in the LCD that was in effect for the dates of service in question does not reflect generally accepted medical practice for treatment of glioblastoma multiforme. The Appellant argues that departure from LCD L34823 is warranted based on significant evidence of general medical acceptance of TTFT as a safe and effective treatment option for glioblastoma, the DAB's May 28, 2019 action, the revised LCD L34823 effective for services performed on or after September 1, 2019.

Subject to certain exclusions, Medicare covers items and services that are reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member, and items and services reasonable and necessary for the prevention of illness. Social Security Act, §§ 1812(a), et seq.; 1862(a)(1)(A)(B). The procedure at issue in this case fits into the broad category of items and services covered by original Medicare.

Medicare also has numerous specific exclusions of items and services that are not covered. 42 U.S.C. § 1395y(a). Items and services which are not reasonable and necessary for the diagnosis and treatment of illness or injury, or to improve the functioning of a malformed body member, or which are not reasonable and necessary for the prevention of illness, are excluded from coverage, along with other numerous specific items that are not covered. The procedure at issue in this case is not excluded from coverage by 42 U.S.C. § 1395y(a). Historically, in making coverage determinations, CMS has interpreted the terms "reasonable and necessary" to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995). FDA approval alone does not generally entitle a procedure or device to Medicare coverage. 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003).

Therefore, the issue in this case is whether TTFT is reasonable and necessary for the treatment of the Enrollee's glioblastoma multiforme, as the term "reasonable and necessary" has been defined by CMS. The CMS Medicare Program Integrity Manual (CMS Pub. 100-08) (MPIM) states that a procedure is reasonable and necessary if it is safe and effective, appropriate, and not experimental. The LCD in effect for the dates of service in question, LCD L34823, states that "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary."

The Appellant argues that the LCD is not supported by the current research, and that the current research, as well as the FDA's October 2015 approval of TTF for treatment of glioblastoma multiforme, and the revised LCD L34823 effective for services performed on or after September 1, 2019, establishes sufficient cause for the ALJ to depart from the LCD that was in effect during the dates of service at issue.

The Appellant is correct that LCD L34823 does not refer to any studies after 2013, and does not mention the FDA's approval of TTFT for treatment of glioblastoma multiforme. The Appellant, however, is not challenging the validity of the LCD in this appeal. Pursuant to 42 C.F.R. § 405.1062(c), this is not the forum in which to make that challenge.

According to 42 C.F.R. § 405.1062, an ALJ is not strictly bound by the LCD, but must give substantial deference to it. However, Section 405.1062 expressly states that an ALJ does not have authority to either "set aside" an LCD or "review the validity" of an LCD in a claim appeal. Section 405.1062 does grant such authority to the DAB and its distinct ALJs under 42 CFR Part 426, in the distinct process for an LCD appeal.

The instant case is a "claim appeal" and not a Part 426 LCD appeal. Here, the Appellant requests that the LCD be deemed unsupported by current medical consensus and literature and therefore inapplicable. To undertake a review of the foundational support for an LCD and declare it broadly unfounded or infirm is to have undertaken a "review of its validity." This is distinct from the ALJ's ability to decline to apply—without questioning its validity—an LCD to the particular circumstances in an individual case.

In its thorough and well-reasoned decision in M-15-1354, *In re BlueCross BlueShield of North Carolina*, MAC (Jan. 2016), the Medicare Appeals Council emphasized that an argument that LCD L34823 is insufficiently supported or detailed, "amounts to a categorical rejection of the substance and validity of the LCD," (which would exceed an ALJ's authority) rather than an argument that the LCD should not be followed on the facts of a particular case (which is within and ALJ's authority). *Id.* at 7. While the ALJ is not bound by this non-precedential Council decision, the ALJ here concurs with and adopts its rationale. Although that and another recent and similar Council decisions were Part C cases, the ALJ finds this distinction inconsequential, as the decision in the instant case relies upon terms of 42 CFR 405.1062, which are not limited in applicability to only Part B or Part C cases.

The record here lacks the evidence to overcome the substantial deference owed to the LCD. The ALJ agrees with the Council's reasoning detailed above. To depart from the LCD here, the ALJ would be conducting an impermissibly broad review and therefore rejecting the validity of the LCD rather than finding a case-specific reason for deviation. Finding an LCD to be wholly and categorically outdated, unfounded, in need of broad revision, or otherwise infirm is an act wisely

reserved for another forum better suited for broadly applicable policy declarations. The ALJ declines to exceed their authority by reviewing the validity of or categorically rejecting the LCD at issue.

At the hearing, Appellant's counsel indicates that the process for reviewing and challenging an LCD has proven not to be timely and adequate. Ms. Parrish notes that LCD L34823 has not been timely updated to reflect critical and more recent clinical studies. This ALJ acknowledges and respects Ms. Parrish's position. The quality of the record developed and the arguments presented by Appellant are outstanding. Unfortunately, the ALJ nonetheless cannot concur with deviation. As discussed above, the ALJ finds a lack of authority to review the validity of an LCD and/or declare it broadly unsupported (rather than deviate from it on a case specific basis). Appellant fails to cite any statute or regulation that expands this limited authority of an OMHA ALJ based upon need, lack of alternative remedy, or shortcomings of the appropriate jurisdiction for LCD review, challenge, and modification. This ALJ firmly believes that 42 C.F.R. § 405.1062 does not grant an ALJ authority to find an LCD infirm, inadequately supported, or otherwise wholly invalid—such undertaking involves an ALJ "review of validity" expressly prohibited by regulation. The recent DAB ALJ order reaffirms that such a wholesale, categorical consideration of the validity of an LCD is within the jurisdiction of an entirely distinct group of adjudicators. Any failure of those distinct avenues to achieve timely and appropriately repeal or amendment of an LCD does not expand this ALJ's limited jurisdiction.

Based on the foregoing, pursuant to LCD L34823 effective for the dates of service at issue, the services here are not reasonable and necessary and there is no coverage for the TTFT to treat the Appellant's glioblastoma multiforme.

Liability

Under § 1879 of the Act, the Medicare program makes payment for non-covered services when neither the beneficiary nor the supplier knew, or could reasonably have been expected to know, that the items or services would be found non-covered on the grounds that they were not medically reasonable and necessary. A provider must give the beneficiary written notice that Medicare will not pay, before the services are provided. MCPM, Pub. 100-04, Ch. 30, § 30.1. The record does not include an Advance Beneficiary Notice (ABN) or any other indication that the Beneficiary knew or could have been reasonably expected to know that the items in question would be excluded from coverage. The supplier received CMS notices and is responsible for knowing Medicare regulation. 42 C.F.R. § 411.406(e). The supplier is responsible for knowing that the disputed services were not medically reasonable and necessary. Thus, the supplier remains responsible for the non-covered charges.

CONCLUSIONS OF LAW

This decision is **UNFAVORABLE** for the Appellant. After careful consideration of all the evidence, the ALJ decides that Medicare Part B coverage and payment does not exist for the Optune® TTFT (tumor treating field therapy) electrical stimulation device (HCPCS code E0766) provided to the Beneficiary on monthly rental periods beginning April 5, 2018; May 5, 2018; and June 5, 2018. The supplier remains liable for the non-covered costs.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: SEP 05 2019

Bruce MacDougall
U.S. Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8393258352**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Bruce MacDougall** **Administrative Law Judge**

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents	438
2	Medical Records/Evidence Received by CMS Contractors	85
3	Request for ALJ Hearing	10
4	OMHA Proceedings	15
5	Documents received after the Request for Hearing	34

Dated: September 5, 2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____ . I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

EXHIBIT E

Docket Number: M-19-2719

Escalation Request

Appeal Information

Appellant name

Lynn Oxenberg

Appellant type

BENEFICIARY

Appellant representative

Debra Parrish

ALJ appeal number

1-8393258352

ALJ decision date

09/05/2019

Medicare contractor

Claim type

Part B

Service type

DME items

Case involving an overpayment?

No

Overpayment

Amount in controversy

$63,000

Date or period of service start

04/05/2018

Date or period of service end

06/05/2018

#	Document Name	Uploaded By	Date Uploaded
1	**dab101.pdf** [148 KB] Request for Review (Form DAB-101)	Tanya Terza	09/09/2019 04:01 pm
2	**AOR_signed.pdf** [83 KB] Appointment of Representative (Form CMS-1696)	Tanya Terza	09/09/2019 04:02 pm
3	**ALJ_Decision_19-127_(Oxenberg)_9.5.19.pdf** [934 KB] Copy of ALJ Decision/Dismissal Order	Tanya Terza	09/09/2019 04:02 pm

#	Document Name	Uploaded By	Date Uploaded
4	**MAC_appeal_(Oxenberg)_9-9-19.pdf** [444 KB] Memorandum or brief or other written statement in support of your appeal	Tanya Terza	09/09/2019 04:05 pm
5	**Escalation_Request_12-31-19_(Oxenberg).pdf** [3 MB] Other	Tanya Terza	12/31/2019 10:50 am

HHS Headquarters

U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Toll Free Call Center: 1-877-696-6775

PARRISH LAW OFFICES

788 Washington Road
Pittsburgh, Pennsylvania 15228-2021
www.dparrishlaw.com

412.561.6250
Fax 412.561.6253
E-mail: info@dparrishlaw.com

December 31, 2019

VIA E-file

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, DC 20201

RE: Request for Escalation
Appellant/Medicare Beneficiary: Lynn Oxenberg
HICN: 7YD3XK0MA81
ALJ Decision Date: Sept. 5, 2019
ALJ Appeal No.: 1-8393258352
DOS: 4/5/18 through 6/5/18
Council No.: M-19-2719 (filed Sept. 9, 2019)
Our Ref: 19-127

Dear Medicare Appeals Council:

Ms. Lynn Oxenberg has received three favorable ALJ decisions finding TTFT meets Medicare coverage criteria for her. See ALJ Nos. 1-8452468241, 1-8651098761 and 3-8686737644. The Secretary chose not to appeal the decisions and each of them has become final. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues with respect to Ms. Oxenberg. As noted by a unanimous Supreme Court, "We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality." *See Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). The application of issue preclusion would not work as basic unfairness against the Secretary and there are no special circumstances that would make it unfair to apply the doctrine.

The above-captioned Medicare beneficiary appeal has been pending for more than 90 days. Accordingly, pursuant to 42 C.F.R. §405.1132, Ms. Oxenberg requests escalation of the above-captioned claims to District Court.

Sincerely,

Debra M. Parrish

Debra M. Parrish for
Medicare Beneficiary Lynn Oxenberg

Enclosures (3)
cc: Lynn Oxenberg
Novocure
C2C

19-129

RECEIVED JUN 06 2019

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Kansas City Field Office
601 East 12th Street, Suite 221
Kansas City, MO 64106
816-599-3300 (Main)
816-599-3300 (ALJ Strafuss Team)
816-527-0115 (Fax)
844-566-6258 (Toll Free)

Date: June 3, 2019

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 1-8452468241

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

L. OXENBERG

C2C Innovative Solutions, Inc.
DME QIC Appeals--ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

NOVOCURE INC.
195 Commerce Way
Portsmouth, NH 03801

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City Field Office
Kansas City, Missouri

Appeal of:	**L. Oxenberg**	ALJ Appeal No.:	**1-8452468241**
Enrollee:	**L. Oxenberg**	Medicare Part:	**B**
HICN:	******6114A**	Before:	**Thomas C. Strafuss** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FAVORABLE** decision is entered for Appellant, L. Oxenberg.

PROCEDURAL HISTORY

Appellant submitted a claim to Noridian Healthcare Solutions, the Medicare Administrative Contractor ("Contractor") with jurisdiction, for electrical stimulation treatment (E0766, tumor treatment field therapy) for dates of service of July 5, 2018; August 5, 2018; September 5, 2018; and October 5, 2018. (Exh. 1, pp. 1-12) The claim was denied initially and at the redetermination level. (*Id.*) C2C Solutions, Inc., a Qualified Independent Contractor ("QIC"), upheld the Contractor's determination in a decision issued March 19, 2019. (*Id.*)

On April 10, 2019, the Office of Medicare Hearings and Appeals ("OMHA") received Appellant's timely request for a hearing before an Administrative Law Judge ("ALJ"). The requested hearing was conducted on May 28, 2019. Debra Parrish, attorney, appeared on behalf of the Appellant and Julie Miles, R.N., appeared telephonically on behalf of Novocure. Noridian submitted a position paper. The case file was admitted into the record.

ISSUE

Whether all Medicare coverage requirements have been met warranting payment under Title XVIII of the Social Security Act ("the Act"), and, if coverage requirements have not been met, whether the limitation of liability provisions in § 1879 are applicable.

FINDINGS OF FACT

The following facts were established by a preponderance of the evidence:

1. Appellant, a 68 year old female, has been diagnosed glioblastoma multiforme. (Exh. 2, pp. 1-64; Exh. 3, pp. 1-8) Appellant is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device (Optune) for brain cancer treatment provided through Novocure. (*Id.*)

2. On December 6, 2018, Noridian Healthcare Solutions denied Appellant's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment. (Exh. 1, pp. 26-30) Noridian Healthcare Solution's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)

3. On March 19, 2019, the QIC examined Appellant's claim and affirmed Noridian Healthcare Solution's denial of coverage. (Exh. 1, pp. 1-12)

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

A party dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services, provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. *See* Social Security Act (the Act), Title XVIII, § 1869(b)(1)(A); *see also* 42 C.F.R. § 405.1014. The Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, unless later reviewed by the Medicare Appeals Council. *Id.*

To be considered timely, the request for hearing must be received by OMHA within sixty days after an appellant receives the QIC's reconsideration decision. An appellant is presumed to have received the QIC's reconsideration five days after the date noted on the first page of the reconsideration unless there is evidence to the contrary. 42 C.F.R. § 405.1002(a)(3).

B. Scope of Review

The ALJ considers all issues not decided entirely in the appellant's favor at any prior level of review. 42 C.F.R. § 405.1032. The ALJ may give notice to the parties if any other issue will be addressed at the hearing. *Id.* The ALJ may also issue a decision on the record on his or her own initiative if the evidence in the hearing record supports a fully favorable finding. 42 C.F.R. § 405.1000(g) and § 405.1038(a).

C. Standard of Review

The ALJ conducts a *de novo* review of each claim at issue. 42 C.F.R. § 405.1000(d) and Section 557 of the Administrative Procedures Act. A *de novo* review requires the ALJ to review and evaluate the evidence without regard to the findings in the prior determinations on the claim and make an independent assessment in reliance upon the evidence and controlling laws. All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on the ALJ. 42 C.F.R. § 405.1063.

An appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence (satisfied through the submission of sufficient evidence in accordance with Medicare rules). *See* § 1814(a)(1), § 1815(b), and § 1833(e) of the Act; *see also* 42 C.F.R. §424.5(a)(6), § 405.1018, § 405.1028, and § 405.1030.

II. Principles of Law

A. Statutes and Regulations

The Social Security Act of 1965 ("The Act") implements a social insurance program for qualifying beneficiaries. The Act also delegates the authority to create Medicare Policy to the Secretary of the U.S. Department of Health and Human Services ("DHHS"). This policy comes in the form of standards issued in the Code of Federal Regulations ("C.F.R"). In addition to the Act and the policies in the C.F.R., the Medicare Program also is governed by the Federal Register ("F.R."), National Coverage Determinations, and the Centers for Medicare & Medicaid Services ("CMS") rulings. Though they do not have the force of law the previous sources carry, Administrative Law Judges ("ALJ") give substantial deference to Medicare transmittals and Medicare Manuals, and Local Coverage Determinations ("LCD"). LCDs are created by a Medicare contractor and they detail Medicare coverage for certain items or services.

According to Section 1862(a)(1) of the Act, "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services which, except for items and services described in a succeeding subparagraph, are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Furthermore, according to § 1833(e) of the Act, "No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Section 1832(a) of the Act states that under Medicare part B, an individual is entitled to Medicare coverage for "medical health and other health services." According to § 1861(s), of the Act, "medical health and other services" includes "durable medical equipment" ("DME"), which meets the following criteria as detailed under 42 C.F.R. § 414.202:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

42 C.F.R. § 410.38 articulates the following scope and conditions for DME: "Medicare part B pays for the rental or purchase of durable medical equipment, including iron lungs, oxygen tents, hospital beds, and wheelchairs, if the equipment is used in the patient's home or in an institution used as a home."

The Centers for Medicare & Medicaid Services ("CMS") has developed the Healthcare Common Procedure Coding System ("HCPCS") to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). Medicare reimbursement is contingent upon a supplier using HCPCS codes when filing claims for items or services provided.

B. Policy and Guidance

Though not binding on ALJs administering Medicare appeals, manuals and rulings issued by the Centers for Medicare and Medicaid Services ("CMS") are used in implementing the Medicare program. ALJs must give the manuals and rulings substantial deference. 42 C.F.R. § 405.1062(a). If an ALJ declines to follow a policy in a particular case, the ALJ must explain the reasons why the policy was not followed. 42 C.F.R. § 405.1062(b).

Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states:

> Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

ANALYSIS

Appellant, a 68 year old female, has been diagnosed glioblastoma multiforme. (Exh. 2, pp. 1-64; Exh. 3, pp. 1-8) Appellant is now requesting approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device (Optune) for brain cancer treatment provided through Novocure. (*Id.*)

On December 6, 2018, Noridian Healthcare Solutions denied Appellant's request for approval for the payment of tumor treatment field therapy through the use of an electrical stimulation device for brain cancer treatment. (Exh. 1, pp. 26-30) Noridian Healthcare Solution's reason for denial was that Local Coverage Determination ("LCD") L34823 regarding tumor treatment field therapy states that tumor treatment field therapy (E0766) will be denied as not reasonable and necessary. (*Id.*)

On March 19, 2019, the QIC examined Appellant's claim and affirmed Noridian Healthcare Solution's denial of coverage. (Exh. 1, pp. 1-12)

The Medicare Contractors CGS Administrators, LLC, and Noridian Healthcare Solutions, currently have a LCD L3482. As previously noted, that LCD simply states that tumor treating field therapy will be denied as not reasonable and necessary. There is no additional detail or guidance contained within the LCD as to why tumor treatment field therapy should not be compensated by Medicare. The only substance is a reference section entitled "Sources of Information and Basis for Decision." That section lists several citations which presumably support the summary conclusion that tumor treating field therapy is not reasonable and necessary. The list is noteworthy in that the most recent citation is from 2013.

Pursuant to section 1869(f)(2) of the Act, Administrative Law Judges are generally required to give substantial deference to Local Coverage Determinations. If an ALJ does not follow an applicable LCD, an explanation must be given. The undersigned ALJ deviates from the current LCD for the reasons discussed herein.

The FDA issued a premarket approval of Optune (a tumor treatment field therapy device) consistent with the prescribed use by the treating physician on November 2, 2015. (Exh. 1, pp. 1744-1752)[1] FDA approval generally means the treatment has been deemed safe and effective. The most recent phase three clinical trial submitted by Novocure,[2] published in December 2015, shows that this treatment is effective because it significantly prolongs the disease progression of glioblastoma, and increases the overall odds of survival. (Exh. 1, pp. 1733-1743) This study was also updated with new data and analysis showing continued positive results in articles dated December 19, 2017, and February 1, 2018. (Exh. 1, pp. 1713-1732) Further, the 2018 National Comprehensive Cancer Network ("NCCN") Guidelines allow for alternating use of electric field therapy with Temozolomide when treating glioblastoma. (Exh. 2, pp. 1709-1712.)

Additionally, there is a proposed LCD currently in the comment period that would cover tumor treatment field therapy, and the Appellant in this case would fit within the very specific and limited parameters set out in the proposed LCD. (Exh. 2, pp. 1-64; Exh. 4, 24-38; Hearing testimony.) Specifically, there must be: a newly diagnosed and confirmed glioblastoma multiforme; the patient must have received initial treatment with maximal debulking surgery followed by chemotherapy and radiation; initiate tumor treatment field therapy within 7 weeks from last dose of concomitant chemotherapy or radiation; receive care for glioblastoma multiforme at a National Cancer Institute-designated comprehensive cancer center, designated cancer center, or designated cancer research network facility; no evidence of cancer progression; maintain a Karnofsky Performance Score of at least 70 or greater; and use tumor treatment field

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[1] The FDA had issued an earlier approval for Optune (NOVOTFF -100A System) on May 6, 2011. The approval was limited to the recurrence of glioblastoma multiform after receiving chemotherapy. The current FDA approval includes newly diagnosed GBM following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy. (*Id.*)

[2] Stupp R., Taillibert S., Kanner A., et al. Maintenance Therapy With Tumor-Treating Fields Plus Temozolomide vs Temozolomide Alone for Glioblastoma: A Randomized Clinical Trial. *JAMA*. 2015; 314(23): 2535-2543. Doi:10.1001/jama.2015.16669. *See* http://jama.jamanetwork.com/article.aspx?articleie=2475463

therapy for at least 18 hours per day. Continued coverage beyond first 3 months requires a face-to-face clinical reevaluation with objective evidence of adherence to treatment. (*Id.*)

Here, the Appellant underwent surgery for glioblastoma multiforme on December 13, 2017, and she was on Temodar (Temozolomide) and radiation until intolerance developed. The brain cancer was Grade IV per the World Health Organization designation. The evidence shows a Karnofsky Performance Score of 90 % or greater with tumor treatment field therapy use around 22 hours per day. There has been no evidence of tumor progression. Initiation of tumor treatment field therapy occurred in a timely manner. The Appellant has been receiving treatment at an approved facility. Finally, the evidence shows continued follow up with a face-to-face clinical reevaluation with objective evidence of compliance. (Exh. 2, pp. 1-64 and hearing testimony).

In summation, the Appellant suffers from glioblastoma, which is the very condition/cancer this device is designed to treat. When all taken together the documentation supports the conclusion that the Optune device is safe and effective and no longer experimental or investigational. Therefore, while the ALJ does not reject the current LCD, the ALJ declines to give it controlling weight. The ALJ concludes that tumor treating field therapy was medically reasonable and necessary in this case, and Medicare covers this service.

The undersigned concludes that Medicare coverage is available for the tumor treatment field therapy requested by the Enrollee. The services requested are covered under Medicare Part B and thus Medicare coverage must be approved.

CONCLUSIONS OF LAW

Based on the evidence of record, the undersigned ALJ finds that Medicare Part B coverage does exist for electrical stimulation for cancer treatment (E0766, tumor treatment field therapy) provided to the Beneficiary for dates of service of July 5, 2018; August 5, 2018; September 5, 2018; and October 5, 2018.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim herein in accordance with this decision.

SO ORDERED,

Dated: JUN 0 3 2019

Thomas C. Strafuss
U.S. Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Kansas City, Missouri

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8452468241**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Thomas Strafuss** Administrative Law Judge

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents	1-1908
2	Medical Records/Evidence Received by CMS Contractors	1-64
3	Request for ALJ Hearing	1-8
4	OMHA Proceedings	1-65

Dated: 06/03/19

Department of Health and Human Services
Office of the Secretary

RECEIVED SEP 09 2019

19-310

OFFICE OF MEDICARE HEARINGS AND APPEALS

Irvine Field Office
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866-495-7414 (Toll Free)

Date: SEP - 5 2019

L. OXENBERG
8302 OLD YORK RD APT A23
ELKINS PARK, PA 19027-1531

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 1-8651098761

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

DEBRA M PARRISH
788 WASHINGTON RD
PITTSBURGH, PA 15228

C2C Innovative Solutions, Inc.
DME QIC Appeals–ALJ
P.O. Box 44006
Jacksonville, FL 32231-4006

DME MAC Noridian Healthcare Solutions, LLC
P.O. BOX 6780
FARGO, ND 58108-6780

Enclosures:

OMHA-152, Decision
OMHA-156, Exhibit List
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8651098761**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Carolyn Cohn-Morros** Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the administrative record and at the hearing, a **FULLY FAVORABLE** decision is entered for **L. OXENBERG** (the "Appellant" or the "Beneficiary").

Procedural History

The appeal is before the undersigned Administrative Law Judge ("ALJ") following prior adverse determinations made by the Medicare Administrative Contractor ("MAC") and by C2C Innovative Solutions, Inc., the Qualified Independent Contractor ("QIC"), which denied the Appellant's claim for coverage for tumor treatment field therapy ("TTFT" or "TTF") (E0766) provided on November 5, 2018, December 5, 2018, and January 5, 2018 (the "dates of service") (Exh. 1).

Following receipt of the QIC's unfavorable decision, the Appellant filed a Request for hearing before an ALJ, which was received by OMHA on June 24, 2019 (Exh. 3, p. 1). The Appellant's Request for an ALJ Hearing satisfies the request for hearing requirement specified in Title 42 Code of Federal Regulations (C.F.R) Section 405.1002(a)(1) because the Appellant's Request for Hearing was filed within 60 days of the QIC's reconsideration decisions (Exhs. 1 and 3). The Appellant waived the right to receive notice of hearing at least 20 calendar days before the date of the hearing (Exh. 4).

On August 15, 2019, a telephonic hearing was held in this matter in Irvine, California (Hearing CD). Ms. Debra Parrish, Esq. appeared and argued on behalf of the Appellant. Mr. Timothy Parks, R.N., the Clinical Appeals Specialist of NovoCure, also appeared and testified on behalf of the Appellant. The MAC and QIC did not appear at the scheduled hearing. No other parties appeared at the hearing. All of the Exhibits were admitted into evidence without objection.

Issues

1. Whether the tumor treatment field therapy (TTFT) device, specifically the electrical stimulation center treatment (E0766), provided to the Appellant on the dates of service is covered by Medicare.

2. If not, whether the waiver of liability provisions contained in Sections 1879 of the Social Security Act (the "Act") apply, and to whom.

Findings of Fact

1. The Appellant was diagnosed with glioblastoma (i.e. a fast growing brain tumor) in December 2017 and she received surgery, chemotherapy, and radiation (Exh. 2, pp. 1-30). She completed chemotherapy radiation in February 2018 (*Id.* at 4).

2. She was prescribed TTFT to treat the Appellant's cancerous brain tumor and by April 27, 2018, she reported that she was using it 22 hours a day (Exh. 2, p. 22). The Appellant indicated that she had no scalp issues and her neuropathic pain was better (*Id.*).

3. On July 6, 2018, the magnetic resonance imaging (MRI) scan of her brain showed a slowly increasing size of neoplasm in her right lateral temporal lobe (Exh. 2, p. 19). By July 27, 2018, the MRI scan showed no overt evidence of progressive neoplasm (*Id.* at 17). Her doctor noted that the Appellant was doing well with the TTFT and recommended continuing treatment (*Id.*)

4. On September 14, 2018, the Appellant reported that she continued to do well with the TTFT and was "very active" (Exh. 2, p. 2). Her doctor noted that the Appellant incurred a liver injury with another treatment called Temodar, therefore, they proceeded with TTFT as the only maintenance therapy (*Id.*)

5. Glioblastoma multiforme (GBM) is the most prevalent malignant brain tumor in adults. Survival at initial presentation is approximately 10 months, and upon recurrence, approximately six month, even with aggressive chemotherapy. Because it is extremely rare for glioblastoma to metastasize, it is efficient to treat the disease with regional therapy as part of the treatment strategy (Exh. 4).

6. Optune, formerly known as NovoTTF-100A System, is durable medical equipment that delivers alternating electric fields or Tumor Treating Fields to the brain. The device consists of an electric field generator that is connected to four insulate transducer arrays. The arrays are place on the patient's scalp and deliver the Tumor Treating Fields Therapy (or TTFT) to the patient's glioblastoma. The fields slow the replication of the cancer cells or stop their growth all together. Optune has been approved by the United States (U.S.) Food and Drug Administration (FDA) to deliver TTFT therapy (Exh. 4).

7. The Appellant submitted a Review Article entitled, *"NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: randomized phase III trial of a novel treatment modality,"* in support of its position (Exh. 2, pp. 1400-1410). Thirty (30)

physicians from various universities and hospitals across the globe, including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTF therapy for patients diagnosed with glioblastoma. As expected, conventional chemotherapy toxicity caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTF therapy. Furthermore, multiple animal experiments showed the "enhanced affect [when] TTF is combined with chemotherapy." Because of this successful animal trial, the U.S. and Europe have approved this device for the treatment of glioblastoma (*Id.*).

8. The Appellant submitted a randomized clinical trial entitled, *"Maintenance Therapy with Tumor-Treating Fields plus Temozolomide vs. Temozolomide Alone for Glioblastoma"* in support of its position. (Exh. 2, pp. 1322-1331). The clinical trial included 695 patients with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. This clinical trial found that by adding TTFT with Temozolomide chemotherapy, it "*significantly* prolonged progressive-free and overall survival" (*Id.*).

9. The Appellant submitted an extensive clinical oncology report entitled, "*Clinical Cancer Advances 2018: Annual Report on Progress against Cancer from the American Society of Clinical Oncology*," from the Journal of Clinical Oncology, which discussed cancer advances in 2018. This article addressed glioblastoma patients treated with TTFT. Clinical research found that the "risk of death" was reduced by 37% for patients using the TTFT device as compared to patients using chemotherapy alone. Additionally, TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 2, pp. 217-233).

10. The Appellant submitted a case report entitled, "*Long-term survival of patients suffering from glioblastoma multiforme treated with Tumor-Treating Fields*," from the World Journal of Surgical Oncology, which discussed case studies of four patients treated with TTFT. In this case report, two patients with glioblastoma multiforme (GBM) were treated with TTFT and two patients with recurrence glioblastoma multiforme (RGBM) were treated with TTFT. Consequently, after 7 years, the two patients with GBM and the two patients with RGBM were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence." (Exh. 2, pp. 1314-1321).

11. The Appellant submitted numerous fully favorable decisions by ALJs addressing TTF therapy. This Exhibit was 1303 pages and it included both Part C and Part B appeals. (Exh. 1, pp. 39-1256).

12. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields) cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields.

Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or *reversing* this disease."[1]

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Section 1869(b)(1)(A) of the Act.

In implementing this statutory directive, the Secretary has delegated authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *See* 74 Fed. Reg. 65296 (December 9, 2009). A hearing before an ALJ is available only if the remaining amount in controversy meets the jurisdictional amount. 42 Code of Federal Regulations (C.F.R) § 422.600(b). A request for hearing is timely if filed within sixty days after receipt of the reconsideration decision. 42 C.F.R. § 422.602(b).

B. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

C. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

An ALJ is bound by statutes, regulations, national coverage determinations ("NCD"), and Medicare Rulings. (42 C.F.R. §§ 405.4060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination ("LCD") or Medicare program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a

[1] https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

particular case. (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. (42 C.F.R. § 405.1062(b).)

Section 1862(a)(1)(A) of the Social Security Act ("Act") provides that notwithstanding any other provisions of title XVIII of the Act, items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from coverage.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies *not binding* on the ALJ or attorney adjudicator and Council provides:

> (a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.
>
> (b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.
>
> (c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

> (a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.
>
> (b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.
>
> (c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R §426.310 LCD and NCD reviews and individual claim appeals provide:

> (a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

> (b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 provides who may challenge an LCD or NCD.

> (a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.
>
> (b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

Future LCD L3482, which is effective on September 1, 2019 – Tumor Treatment Field Therapy (TTFT) provides in part:

> Coverage Indications, Limitations, and/or Medical Necessity
> . . .
> The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.
>
> In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:
>
> For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
>
> **Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.** (Emphasis added).
> . . .

HCPCS Codes

. . .

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

. . .

Policy Article A52711- Tumor Treatment Field Therapy (TTFT) provides in part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.

Separate billing of supplies and/or accessories will be denied as unbundling. Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES
Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2016 provides that alternating electric field therapy for glioblastoma and is a category 2B recommendation.

The related Policy Article **A52711** states in pertinent part:

> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
>
> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
>
> Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.
>
> Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling.
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>
> Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

ANALYSIS

The issue on appeal is whether the Appellant is entitled to coverage for the TTFT device (HCPCS code E0766) provided on the dates of service under Medicare Part B.

Medicare makes payment on items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body

member." *See* § 1862(a)(1) of the Act. All Medicare claims for payment must be supported by sufficient information and documentation. *See* § 1833(e) of the Act.

The Appellant's attorney representative, Ms. Debra Parrish, stated that the Appellant was diagnosed with a glioblastoma in December of 2017. The Appellant received surgery, chemotherapy and radiation. Ms. Parrish stated that the Appellant was prescribed the Optune device to deliver TTFT treatment to her glioblastoma. Ms. Parrish stated that the Contractor denied the claims stating that the device was not reasonable and necessary. She explained that the QIC found that the studies do not document the effectiveness of the device, that the effectiveness of the device was not quantified for this Appellant, and that the LCD requirements were not met. Ms. Parrish argued that the studies show that the device is indeed effective; so much so that one trial was suspended due to its effectiveness. She argued that the evidence on the effectiveness of the device at issue is overwhelming. Ms. Parrish went onto state that the device received a level 1 approval, which is a unanimous agreement that the device is effective. Ms. Parrish argued that the other LCDs that apply to TTFT have been retired in 2015. Without an LCD, Medicare coverage is determined by peer-reviewed literature, a consensus of experts, and whether or not the relevant medical community has adopted the technology. Ms. Parrish asserted that the retired LCDs do not apply to patients who have recently been diagnosed with glioblastoma. Also, Ms. Parrish argued that the LCD is inconsistent with current medical literature and it is not substantiated by the medical community (Hearing CD).

In her position brief, Ms. Parish submitted the Local Coverage Determination Tumor Treatment Field Therapy (TTFT) (L34823) (Exh. 4). The future LCD L34823, which is effective on September 1, 2019, provides that TTFT (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme when the following criteria are met:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery, followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy; and,
4. The beneficiary is receiving care for GBM at a National Cancer Institute-designated Cancer Center, National Cancer Institute-designated Comprehensive Cancer Center, or National Cancer Institute-designated Cancer Research Network facility; and,
5. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
6. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
7. The beneficiary will use TTFT for at least 18 hours/day.

At the hearing, Ms. Parrish noted that the Appellant meets all the criteria in the future LCD. (Hearing CD).

Mr. Timothy Parks, the Clinical Appeals Specialist of NovoCure, appeared and testified on behalf of the Appellant. Mr. Parks testified that the Appellant suffered from a newly diagnosed glioblastoma. On December 2017, an MRI scan showed the tumor and the Appellant underwent chemotherapy. By February 2018, she completed the chemotherapy treatment and started Optune with chemo temozolomide on April 15, 2018. Mr. Parks testified that the Appellant has since had

a stable MRI on July 12, 2018. He asserted that the Appellant was using the TTFT 90 percent of the time and her KPS was now 90 after the Optune treatment (Hearing CD).

The testimony provided by Mr. Parks and the argument provided by Ms. Parrish were trustworthy, credible, persuasive, and supported by the record.

After carefully considering the evidence in the record as well as the arguments and testimony presented at the hearing, the ALJ finds that the TTFT device was medically reasonable and necessary for the Appellant and Medicare coverage shall be allowed.

First, TTFT has been approved by the Food and Drug Administration (FDA)[2] since April 2011. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease."[3] The FDA asserts that cancer growth is slowed and can be reversed after using this device.

Second, the Beneficiary meets the criteria for future LCD L34823, which is effective on September 1, 2019. Until such time as the future LCD is effective, there is no LCD in effect and if the retired LCDs (L34734, L34665, L34730, and L34738) were in in effect, the ALJ would decline to follow them for a multitude of reasons. The retired LCDs stated that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." Nevertheless, the QIC based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. The retired LCDs categorically deny that *any* TTFT treatment is reasonable and necessary under *any* circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. The retired LCDs are noticeably outdated and ignore medically relevant data from the most prestigious medical institutions in the world including medical opinions, research articles, peer-review studies, university research, clinical oncology reports, etc., and it ignores the medical findings of the FDA in the last eight years. The current scientific data and research supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant. TTFT is not experimental or investigational but has been approved by the FDA. Furthermore, the sparse nature of any medical reasoning in the retired LCDs provide additional reasons not to follow it here, where the medical evidence, testimony, and argument so

[2]The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, such as the Appellant, with newly-diagnosed GBM. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm.

[3] https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

overwhelmingly support the Appellant's case. Regardless of the guidance provided by the retired LCDs, a departure from the guidelines set forth in these LCDs is required based upon the Appellant's serious condition, the great benefits realized by the Appellant after using this device, and the vast medical findings and research in the last decade. Furthermore, federal regulations *permit* ALJs to decline to follow a local coverage policy. 42 C.F.R. Sec. 405.1062.

Third, the evidence supports the need for this device pursuant to Section 1862(a)(1) of the Social Security Act. Sufficient information was provided to corroborate the Appellant's contentions pursuant to Section 1833(e) of the Social Security Act. *See* 42 C.F.R. § 424.5(a)(6). The Appellant was suffering from a deadly malignant brain tumor and needed the best treatment which could be afforded to her. The Appellant suffered from glioblastoma, which is an aggressive form of brain cancer. She was provided extensive treatment since her diagnosis in December 2017. The Appellant underwent surgery, chemotherapy, radiation, and eventually she was prescribed TTF therapy. The Appellant, on the advice of her treating doctor, seeks coverage for the treatment services furnished by NovoCure. The Optune treatment or NovoTTF-100A System was highly recommended by her doctor. This therapy uses alternating electrical fields to interfere with the rapid growth and division of cancer cells. The Appellant provided over 1,000 pages of medical literature in support of its position. The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for this Appellant.

For example, thirty physicians from universities and hospitals across the globe including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, etc., performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT. They found that conventional chemotherapy treatment caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple experiments suggest the enhanced affect when TTF is combined with chemotherapy (Exh. 2, pp. 1400-1410).

The Appellant also submitted a randomized clinical trial in which 695 patients were treated with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results were very remarkable. The clinical trial concluded that adding TTFT with Temozolomide chemotherapy "*significantly* prolonged progressive-free and overall survival". (Exh. 2, pp. 1322-1331).

The Appellant submitted a clinical oncology report, which discussed cancer advances in 2018. This report discussed glioblastoma patients treated with TTFT and it found that the "risk of death" was reduced by 37% for patients using the TTFT device compared to those who used only chemotherapy. TTFT was also found to double the 5-year survival rate from 5% to 13%. (Exh. 2, pp. 217-243).

The Appellant submitted a case report, which discussed case studies on four specific patients treated with TTFT, two patients with glioblastoma multiforme (GBM) and two patients with recurrence glioblastoma multiforme (RGBM). After seven years these four patients were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence" (Exh. 2, pp. 1314-1321). Thus, after weighing all the evidence, the medical reasonableness and necessity for using such a device to treat the Appellant's condition was clearly warranted. Even though the treatment was very expensive, it is comparable to using expensive chemotherapy drugs, which are not as effective as TTFT.

Fourth, the QIC has provided no medical evidence to cast any doubt on the effectiveness of the TTFT treatment, especially as applied to treating this Appellant. In fact, there is no evidence on the contrary in the record. Furthermore, the QIC and MAC failed to appear and to contest the evidence submitted in the record and presented by the Appellant's representative and witness.

Lastly, the Appellant substantially meets the criteria provided in the future LCD L34823, which is effective on September 1, 2019. Even though the proposed LCD is yet to be effective, coverage in this appeal is consistent with Medicare's policy movement towards coverage of TTFT for glioblastoma. Therefore, for all these reasons, the TTFT device was medically reasonable and necessary, is currently the best treatment for the Appellant's condition and shall be covered pursuant to the provisions of Section 1862(a)(1) of the Social Security Act.

As this decision is fully favorable, the limitation of liability issue is moot and need not be discussed.

CONCLUSIONS OF LAW

1. The Appellant is entitled to coverage for the TTFT (E0766) provided on the dates of service. This device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by the Appellant, and Section 1862(a)(1) of the Social Security Act. Medicare payment shall be allowed on the TTFT device.

2. The limitation of liability under Section 1879 of the Social Security Act does not apply, as the issue is moot.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED

Dated: SEP - 5 2019

Carolyn Cohn-Morros
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, California

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**1-8651098761**
Beneficiary:	**L. OXENBERG**	Medicare:	**Part B**
Medicare No.:	*******6114A**	Before:	**Carolyn Cohn-Morros** **Administrative Law Judge**

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents (pages 39 - 1632 in separate box)	1-38 39 - 1632
2	Medical Records/Evidence Received by CMS Contractors (pages 230-1638 in separate box)	1-229 230- 1638
3	Request for ALJ Hearing	1-14
4	OMHA Proceedings	1-20
5	Documents received after the Request for ALJ Hearing	1-43

Dated: 9/05/19

[1] Some materials in the exhibited record are dual sided. References to the second side include a notation of (reverse). For example, "Ex. 1, p. 1 (reverse)." The second side of a dual sided page is not included in the page count for the page number range.

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Irvine Field Office
19 Technology Drive
Suite 200
Irvine, CA 92618-2364
(866) 495-7414
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October 24, 2019

PARRISH LAW OFFICES
ATTN: DEBRA PARRISH
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: L. OXENBERG
OMHA Appeal Number: 3-8686737644

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.
##PAGEBREAK##
How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this

notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

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Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod.**

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.
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Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.
##PAGEBREAK##

CC: L. Oxenberg

C2C Innovative Solutions, Inc.

Enclosures: Exhibit List

DAB-101 Request for Review of Hearing Decision/Dismissal Order

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of:	**L. OXENBERG**	OMHA Appeal No.:	**3-8686737644**
Beneficiary:	**L. OXENBERG**	Medicare Part:	B
Medicare No.:	*******6114A**	Before:	**Carolyn Cohn-Morros** Administrative Law Judge

DECISION

After careful consideration of all the evidence and arguments presented in the administrative record and at the hearing, a **FULLY FAVORABLE** decision is entered for **L. OXENBERG** (the "Appellant" or the "Beneficiary").

PROCEDURAL HISTORY

The appeal is before the undersigned Administrative Law Judge ("ALJ") following prior adverse determinations made by the Medicare Administrative Contractor ("MAC") and by C2C Innovative Solutions, Inc., the Qualified Independent Contractor ("QIC"), which denied the Appellant's claim for coverage for tumor treatment field therapy ("TTFT" or "TTF") (E0766) provided on February 5, 2019, March 5, 2019, April 5, 2019, and May 5, 2019 (the "dates of service") (Exh. 1, p. 4).

The Appellant filed a timely request for hearing before an Administrative Law Judge ("ALJ") and the amount in controversy satisfies the jurisdictional requirement for this appeal.

The Appellant requested in writing that the Administrative Law Judge ("ALJ") decide the case without a hearing. The undersigned ALJ hereby grants the Appellant's request and issues this decision pursuant to 42 C.F.R. § 405.1038(b). The entire file is admitted into the record without objection.

ISSUES

1. Whether the tumor treatment field therapy (TTFT) device, specifically the electrical stimulation center treatment (E0766), provided to the Appellant on the dates of service is covered by Medicare.

2. If not, whether the waiver of liability provisions contained in Sections 1879 of the Social Security Act (the "Act") apply, and to whom.

APPLICABLE LAW AND POLICY

I. ALJ Review Authority

A. Scope of Review

The issues before the ALJ include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. However, if evidence presented before the hearing causes the ALJ to question a fully favorable portion of the determination, the ALJ will notify the parties before the hearing and will consider it an issue at the hearing.

B. Standard of Review

An ALJ conducts a de novo review and issues a decision based on the hearing record. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

An ALJ is bound by statutes, regulations, national coverage determinations ("NCD"), and Medicare Rulings. (42 C.F.R. §§ 405.4060(a)(4) and 405.1063.) An ALJ is not bound by a local coverage determination ("LCD") or Medicare program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case. (42 C.F.R. § 405.1062(a).) If an ALJ declines to follow a policy in a particular case, the ALJ decision must explain the reasons why the policy was not followed. (42 C.F.R. § 405.1062(b).)

Section 1862(a)(1)(A) of the Social Security Act ("Act") provides that notwithstanding any other provisions of title XVIII of the Act, items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are excluded from coverage.

42 C.F. R §405.1062 - Applicability of local coverage determinations and other policies *not binding* on the ALJ or attorney adjudicator and Council provides:

> (a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.
>
> (b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.
>
> (c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB

may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

42 C.F.R. §426.300 Review of LCDs, NCDs, and deemed NCDs provides:

(a) Upon the receipt of an acceptable LCD complaint as described in §426.400, an ALJ conducts a review of a challenged provision (or provisions) of an LCD using the reasonableness standard.

(b) Upon the receipt of an acceptable NCD complaint as described in §426.500, the Board conducts an NCD review of a challenged provision (or provisions) of an NCD using the reasonableness standard.

(c) The procedures established in this part governing the review of NCDs also apply in cases in which a deemed NCD is challenged.

42 C.F.R §426.310 LCD and NCD reviews and individual claim appeals provide:

(a) LCD and NCD reviews are distinct from the claims appeal processes set forth in part 405, subparts G and H; part 417, subpart Q; and part 422, subpart M of this chapter.

(b) An aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD or NCD complaint. This reporting obligation continues through the entire LCD or NCD review process.

42 C.F.R. §426.320 provides who may challenge an LCD or NCD.

(a) Only an aggrieved party may initiate a review of an LCD or NCD (including a deemed NCD), or provisions of an LCD or NCD by filing an acceptable complaint.

(b) Neither an ALJ nor the Board recognizes as valid any attempt to assign rights to request review under section 1869(f) of the Act.

B. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than an National Coverage Determination (NCD), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies (LMRPs) or Local Coverage Determinations (LCDs).

ALJs are not bound by LCDs, LMRPs, or CMS program guidance such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

LCD L3482, which was effective on September 1, 2019 – Tumor Treatment Field Therapy (TTFT) provides in part:

> Coverage Indications, Limitations, and/or Medical Necessity
>
> . . .
>
> The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.
>
> In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents that must also be met prior to Medicare reimbursement:
>
> For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.
>
> **Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.** (Emphasis added).
>
> . . .
>
> HCPCS Codes
>
> . . .
>
> E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE
>
> . . .

Policy Article A52711- Tumor Treatment Field Therapy (TTFT) provides in part:

> NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:
>
> For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.
>
> Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.
>
> Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories.
>
> Separate billing of supplies and/or accessories will be denied as unbundling.

Code A4555 is not valid for billing to Medicare. If code A4555 is billed, it will be denied as an invalid code.

CODING GUIDELINES
Code E0766 describes devices that generate electromagnetic fields utilized in the treatment of cancer. The electromagnetic energy generated is transmitted to the body by means of surface electrodes or transducers.

This code is inclusive of all associated supplies necessary for the effective use of code E0766 including, but not limited to, transducers/surface electrodes, lead wires, adhesive patches, connectors, conductive gel and skin preps.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Central Nervous System Cancers Version 1.2016 provides that alternating electric field therapy for glioblastoma and is a category 2B recommendation.

The related Policy Article A52711 states in pertinent part:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary"). Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

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Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

FINDINGS OF FACT AND ANALYSIS

The issue on appeal is whether the Appellant is entitled to coverage for the TTFT device (HCPCS code E0766) provided on the dates of service under Medicare Part B.

Medicare makes payment on items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *See* § 1862(a)(1) of the Act. All Medicare claims for payment must be supported by sufficient information and documentation. *See* § 1833(e) of the Act.

Here, the Appellant was diagnosed with glioblastoma (i.e. a fast growing brain tumor) in December 2017 and she received surgery, chemotherapy, and radiation (Exh. 5, pp. 46-54; Exh. 7, pp. 16-93). She completed chemotherapy radiation in February 2018 (*Id.*). She was prescribed TTFT to treat the Appellant's cancerous brain tumor and by April 27, 2018, she reported that she was using it 22 hours a day (*Id.*). The Appellant indicated that she had no scalp issues and her neuropathic pain was better (*Id.*). On July 6, 2018, the magnetic resonance imaging (MRI) scan of her brain showed a slowly increasing size of neoplasm in her right lateral temporal lobe (*Id.*). By July 27, 2018, the MRI scan showed no overt evidence of progressive neoplasm (*Id.*). Her doctor noted that the Appellant was doing well with the TTFT and recommended continuing treatment (*Id.*). On September 14, 2018, the Appellant reported that she continued to do well with the TTFT and was "very active" (*Id.*). Her doctor noted that the Appellant incurred a liver injury with another treatment called Temodar, therefore, they proceeded with TTFT as the only maintenance therapy (*Id.*). On February 19, 2019, the Appellant's TTFT prescription was renewed (*Id.* at 58). On April 5, 2019, the Appellant underwent an MRI scan, which revealed there was "continued stability and no evidence of tumor progression" (*Id.* at 39).

The Appellant's attorney representative, Ms. Debra Parrish, stated in the Request for Reconsideration, that the Appellant was prescribed the Optune device to deliver TTFT treatment to her glioblastoma (Exh. 7, p. 4). Ms. Parrish stated that the Contractor denied the claims stating that the device was not reasonable and necessary (*Id.*). She explained that the QIC found that the studies do not document the effectiveness of the device, that the effectiveness of the device was not quantified for this Appellant, and that the LCD requirements were not met (*Id.*). Ms. Parrish argued that the studies show that the device is indeed effective; so much so that one trial was suspended due to its effectiveness (*Id.*). She argued that the evidence on the effectiveness of the device at issue is overwhelming. Ms. Parrish went onto state that the device received a level 1 approval, which is a unanimous agreement that the device is effective (*Id.*). Ms. Parrish argued that the other LCDs that apply to TTFT have been retired in 2015 (*Id.*). Without an LCD, Medicare coverage is determined by peer-reviewed literature, a consensus of experts, and whether or not the relevant medical community has adopted the technology (*Id.*).

Ms. Parrish asserted that the retired LCDs do not apply to patients who have recently been diagnosed with glioblastoma (*Id.*). Also, Ms. Parrish argued that the LCD is inconsistent with current medical literature and it is not substantiated by the medical community (*Id.*).

In the Request for Reconsideration, Ms. Parish argued that LCD L34823, which was effective on September 1, 2019, provides that TTFT (E0766) is covered for the treatment of newly diagnosed Glioblastoma Multiforme when the following criteria are met:

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,
2. The beneficiary has received initial treatment with maximal debulking surgery (when feasible), followed by chemotherapy and radiotherapy; and,
3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy; and,
4. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,
5. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,
6. The beneficiary will use TTFT for at least 18 hours/day.

After carefully considering the evidence in the record, the ALJ finds that the TTFT device was medically reasonable and necessary for the Appellant and Medicare coverage shall be allowed.

First, TTFT has been approved by the Food and Drug Administration (FDA)[1] since April 2011. According to the FDA website, "the *breakthrough* finding made by NovoCure was that finely tuned alternating fields of very low intensity, now termed TTFields (Tumor Treating Fields), cause a significant slowing in the growth of cancer cells. Due to the unique geometric shape of cancer cells when they are multiplying, TTFields cause the building blocks of these cells to move and pile up in such a way that the cells physically explode. In addition, cancer cells also contain miniature building blocks which act as tiny motors in moving essential parts of the cells from place to place. TTFields cause these tiny motors to fall apart since they have a special type of electric charge. As a result of these two effects, cancer tumor growth is slowed and can even reverse after continuous exposure to TTFields. Other cells in the body (normal healthy tissues) are affected much less than cancer cells since they multiply at a much slower rate if at all. In addition, TTFields can be directed to a certain part of the body, leaving sensitive areas out of their reach. In conclusion, TTFields hold the promise of serving as a brand new cancer treatment with very few side effects and promising affectivity in slowing or reversing this disease."[2] The FDA asserts that cancer growth is slowed and can be reversed after using this device.

Second, the Beneficiary meets the criteria for LCD L34823, which was effective on September 1, 2019. Before LCD L34823 was effective, there was no LCD in effect and if the retired LCDs (L34734, L34665, L34730, and L34738) were in in effect, the ALJ would decline to follow them for a multitude of reasons. The retired LCDs stated that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." Nevertheless, the QIC based its decision on an LCD that does not contain any discussion, rationale, or any explanation for its conclusions. The retired LCDs categorically deny that *any* TTFT treatment is reasonable and necessary under *any*

1The U.S. Food and Drug Administration, in October 2015, approved an expanded indication for the Optune device by NovoCure for TTF (the treatment at issue in this appeal), to treat patients, such as the Appellant, with newly-diagnosed GBM. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm465744.htm.

2 https://clinicaltrials.gov/ct2/show/study/NCT00916409?show_desc=Y#desc

circumstance without setting forth an underlying basis, discussion, criteria, or rationale for that determination. The retired LCDs are noticeably outdated and ignore medically relevant data from the most prestigious medical institutions in the world including medical opinions, research articles, peer-review studies, university research, clinical oncology reports, etc., and it ignores the medical findings of the FDA in the last eight years. The current scientific data and research supports a finding that TTFT treatment is medically reasonable and necessary for patients like the Appellant. TTFT is not experimental or investigational but has been approved by the FDA. Furthermore, the sparse nature of any medical reasoning in the retired LCDs provide additional reasons not to follow it here, where the medical evidence, testimony, and argument so overwhelmingly support the Appellant's case. Regardless of the guidance provided by the retired LCDs, a departure from the guidelines set forth in these LCDs is required based upon the Appellant's serious condition, the great benefits realized by the Appellant after using this device, and the vast medical findings and research in the last decade. Furthermore, federal regulations *permit* ALJs to decline to follow a local coverage policy. 42 C.F.R. Sec. 405.1062.

Third, the evidence supports the need for this device pursuant to Section 1862(a)(1) of the Social Security Act. Sufficient information was provided to corroborate the Appellant's contentions pursuant to Section 1833(e) of the Social Security Act. *See* 42 C.F.R. § 424.5(a)(6). The Appellant was suffering from a deadly malignant brain tumor and needed the best treatment which could be afforded to her. The Appellant suffered from glioblastoma, which is an aggressive form of brain cancer. She was provided extensive treatment since her diagnosis in December 2017. The Appellant underwent surgery, chemotherapy, radiation, and eventually she was prescribed TTF therapy. The Appellant, on the advice of her treating doctor, seeks coverage for the treatment services furnished by NovoCure. The Optune treatment or NovoTTF-100A System was highly recommended by her doctor. This therapy uses alternating electrical fields to interfere with the rapid growth and division of cancer cells. The Appellant provided over 1,000 pages of medical literature in support of its position. The medical literature is overwhelming in establishing the medical reasonableness and necessity for this device for this Appellant.

For example, the Appellant submitted a Review Article entitled, "*Novo TTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: randomized phase III trial of a novel treatment modality,*" in support of its position. Thirty physicians from universities and hospitals across the globe including Tel Aviv Medical Center, University of Hamburg, and the Cleveland Clinic Foundation, etc., performed comprehensive research on the effectiveness and toxicity of conventional chemotherapy versus TTFT. They found that conventional chemotherapy treatment caused far more gastrointestinal, hematological, and infectious adverse events as compared to TTFT. Furthermore, multiple experiments suggest the enhanced affect when TTF is combined with chemotherapy (Exh. 2, pp. 1390-1400).

The Appellant also submitted a randomized clinical trial entitled "*Maintenance Therapy with Tumor-Treating Fields plus Temozolomide vs. Temozolomide Alone for Glioblastoma,*" in which 695 patients were treated with newly diagnosed glioblastomas in 83 centers in the United States, Canada, Europe, Israel, and South Korea. The results were very remarkable. The clinical trial concluded that adding TTFT with Temozolomide chemotherapy "*significantly* prolonged progressive-free and overall survival" (Exh. 2, pp. 1313-1321).

The Appellant submitted an extensive clinical oncology report entitled, "*Clinical Cancer Advances 2018: Annual Report on Progress against Cancer from the American Society of Clinical Oncology,*" from the Journal of Clinical Oncology, which discussed cancer advances in 2018. This report discussed glioblastoma patients treated with TTFT and it found that the "risk of death" was reduced by 37% for patients using the TTFT device compared to those who used

only chemotherapy. TTFT was also found to double the 5-year survival rate from 5% to 13% (Exh. 2, pp. 207-233).

The Appellant submitted a case report entitled, *"Long-term survival of patients suffering from glioblastoma multiforme treated with Tumor-Treating Fields,"* from the World Journal of Surgical Oncology, which discussed case studies of four patients treated with TTFT. In this case report, two patients with glioblastoma multiforme (GBM) and two patients with recurrence glioblastoma multiforme (RGBM). After seven years these four patients were in "good health" and were "no longer receiving any treatment" coupled with "no clinical or radiological evidence of recurrence" (Exh. 2, pp. 1306-1311). Thus, after weighing all the evidence, the medical reasonableness and necessity for using such a device to treat the Appellant's condition was clearly warranted. Even though the treatment was very expensive, it is comparable to using expensive chemotherapy drugs, which are not as effective as TTFT.

Fourth, the QIC has provided no medical evidence to cast any doubt on the effectiveness of the TTFT treatment, especially as applied to treating this Appellant. In fact, there is no evidence on the contrary in the record. Furthermore, the QIC and MAC failed to appear and to contest the evidence submitted in the record and presented by the Appellant's representative and witness.

Lastly, the Appellant substantially meets the criteria provided in LCD L34823, which was effective on September 1, 2019. The coverage in this appeal is consistent with Medicare's policy movement towards coverage of TTFT for glioblastoma. Therefore, for all these reasons, the TTFT device was medically reasonable and necessary, is currently the best treatment for the Appellant's condition and shall be covered pursuant to the provisions of Section 1862(a)(1) of the Social Security Act.

As this decision is fully favorable, the limitation of liability issue is moot and need not be discussed.

CONCLUSIONS OF LAW

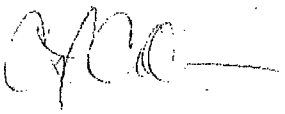
1. The Appellant is entitled to coverage for the TTFT (E0766) provided on the dates of service. This device was medically necessary pursuant to the FDA research and guidelines, the overwhelming medical data submitted by the Appellant, and Section 1862(a)(1) of the Social Security Act. Medicare payment shall be allowed on the TTFT device.

2. The limitation of liability under Section 1879 of the Social Security Act does not apply, as the issue is moot.

ORDER

For the reasons discussed above, this decision is **FULLY FAVORABLE.** The undersigned ALJ directs The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED



Carolyn Cohn-Morros
Administrative Law Judge

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Irvine, CA

Appeal of: **L. OXENBERG**	OMHA Appeal No.: **3-8686737644**
Beneficiary: **L. OXENBERG**	Medicare Part: **B**
Medicare No.: *******6114A**	Before: **Carolyn Cohn-Morros** Administrative Law Judge

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Exhibit Record

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EXHIBIT F

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Miami Field Office
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Suite 1536
Miami, FL 33130-1608
(786) 792-3700
(786) 792-3810 (Direct)
(305) 755-9135 (Fax)
(866) 622-0382 (Toll Free)

October 24, 2019

PARRISH LAW OFFICES
ATTN: DEBRA PARRISH
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: R. LEWIS JR
OMHA Appeal Number: 3-8693279102

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

C2C Innovative Solutions, Inc.
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DEBRA PARRISH
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

Enclosures:

OMHA-152, Decision

DAB-101, Request for Review

OMHA-156, Exhibit List

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, FL

Appeal of: **R. LEWIS JR**	OMHA Appeal No.: **3-8693279102**
Beneficiary: **R. LEWIS JR**	Medicare Part: B
Medicare No.: *******1077A**	Before: **Gerald Hynum** Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, I enter a **FULLY FAVORABLE** on-the-record decision. The tumor treatment field therapy ("TTFT") provided to the Appellant from November 9, 2018, to May 9, 2019, is covered.

PROCEDURAL HISTORY

The Beneficiary/Appellant, R. Lewis, received Tumor Treatment Field Therapy ("TTFT") (E0766) from the Supplier, Novocure, Inc., from November 9, 2018, to May 9, 2019. The Appellant's claim to Medicare was denied by Noridian Healthcare Solutions, a Medicare Administrative Contractor ("Contractor"), upon initial and redetermination. On August 7, 2019, C2C Innovative Solutions, a Medicare Qualified Independent Contractor ("QIC"), upheld the prior denials upon reconsideration review. By correspondence received August 22, 2019, the Appellant made a request for an Administrative Law Judge ("ALJ") hearing before the Office of Medicare Hearings and Appeals ("OMHA").

Exhibits 1 through 5 were admitted into the record without objection. This decision is being issued in the absence of a hearing as careful consideration of all the documents identified in the record has resulted in a decision fully favorable to the Appellant. 42 C.F.R. § 405.1038(a).

ISSUES

Whether the Tumor Treatment Field Therapy ("TTFT") (E0766) received by the Appellant from the Supplier, Novocure, Inc., from November 9, 2018, to May 9, 2019, may be covered under Medicare Part B, and, if not, who is liable for the non-covered charges?

PRINCIPLES OF LAW

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision must be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term which is defined by the Act to include durable medical equipment. Act §§ 1832(a)(1)(B) and 1861(s)(6); 42 C.F.R. §410.10(h). No Medicare payment can be allowed for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A); 42 C.F.R. §411.15(k)(2).

Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than National Coverage Determinations, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 CFR §405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations ("LCDs"). Administrative Law Judges are not bound by LCDs or CMS program guidance but must give substantial deference to these policies if they apply to a particular case. 42 C.F.R. § 405.1062(a). When an ALJ declines to follow a policy in a particular case, the ALJ's decision must set forth the reasons for departing from the policy. 42 C.F.R. § 405.1062(b).

FINDINGS OF FACT

After careful consideration of the entire record, a preponderance of the evidence establishes the following facts:

1. The amount in controversy is in excess of $160.00. The QIC issued an unfavorable reconsideration decision on August 7, 2019 (File 1, p. 1). By correspondence received August 22, 2019, the Appellant made a request for an ALJ hearing before OMHA (File 5, p. 1). Exhibits 1 through 5 were admitted into the record without objection.

2. The Beneficiary, a 67-year-old male, was evaluated by his primary care physician after developing word-finding difficulties in early 2018 and a brain CT showed a left temporal brain mass which was confirmed with an MRI obtained in February 2018 (File 3, pp. 16, 19).

3. On February 27, 2018, the Beneficiary underwent surgical resection and pathology demonstrated that he had grade IV glioblastoma (File 3, p. 16). A physician progress note from April 2018 provides that the Beneficiary was in the midst of current chemoradiation with Temodar which he was tolerating well (*Id.*, p. 22). The physician noted that the plan was to obtain another MRI 4 weeks after radiation is finished and proceed with a minimum of 6 cycles of adjuvant temozolomide and tumor treatment field therapy with the Optune device after the Beneficiary completes radiation therapy (*Id.*).

4. The Beneficiary received TTFT on November 9, 2018; December 9, 2018; January 9, 2019; February 9, 2019; March 9, 2019; April 9, 2019; and May 9, 2019 (File 1, p. 13).

ANALYSIS

The amount in controversy is in excess of $160.00. The reconsideration decision was issued on August 7, 2019, and by correspondence received August 22, 2019, the Appellant made

a request for an ALJ hearing before OMHA. Accordingly, the Appellant's request for a review is timely and the claim satisfies the jurisdictional requirements for an ALJ hearing before OMHA. Exhibits 1 through 5 were admitted into the record without objection. This decision is being issued in the absence of a hearing as careful consideration of all the documents identified in the record has resulted in a decision fully favorable to the Appellant. 42 C.F.R. § 405.1038(a).

The Appellant/Beneficiary was newly diagnosed with glioblastoma, a type of brain cancer, and had surgery, chemotherapy and radiation, and on the dates of service at issue also had Tumor Treatment Field Therapy (TTFT). The TTFT was denied by Medicare.

This Administrative Law Judge conducted a de novo review of the evidence to determine whether the Appellant established the requirements for Medicare coverage. The Appellant's request for an ALJ hearing was timely and satisfied jurisdictional requirements. In this case, this ALJ finds and concludes that the tumor treatment field therapy for treatment of this Beneficiary's glioblastoma for the dates of service was medically reasonable and necessary. First, this ALJ notes that there is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.* In this case, this ALJ declines to follow LCD L34823 for multiple reasons as further discussed.

In general, this ALJ finds that the therapy has been shown to be safe and effective for use in patients with newly diagnosed glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success, as is the case here with this Beneficiary) and it is medically reasonable and necessary to treat the Beneficiary's condition. The relevant LCD in effect at the time of the issuance of the QIC's decision states that tumor treatment field therapy will be denied as not reasonable and necessary. The advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently, reported data from the FDA, phase III clinical trials and NCCN guidelines are available to this ALJ for review and analysis, and that information shows the LCD may be behind the medical literature curve as applied to this patient. First, this ALJ finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence, although FDA approval alone is not determinative of Medicare coverage. Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1 862(a)(l). To be reasonable and necessary, the procedure must be safe and effective and not experimental. The use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. Most commercial health plans now cover TTFT. As such, this ALJ finds that TTFT treatment is generally accepted in the medical

community as safe and effective for the treatment of recurrent glioblastoma based upon the medical literature provided by the Appellant. Although the LCD states that the procedure is not covered, without giving any explanation for the non-coverage, this Judge is not bound by the LCD. *See* 42 C.F.R. 405.1062(a). Based upon the medical evidence this Judge has determined that it is appropriate to depart from the LCD based upon evidence that was not available at the time the LCD was written. Also the applicable LCD has been revised as of September 1, 2019, after the QIC issued its decision in this case, and the revised LCD provides coverage for TTFT treatment of newly discovered glioblastoma. The medical evidence in the record establishes that the Beneficiary had already undergone surgical resection of the tumor and radiation, and the TTFT treatment is the only treatment available to further prolong his life and it has prolonged his life. For all of the reasons stated above, this Judge finds that the Optune (TTFT) system has been shown to be safe and effective, and it was and is medically necessary for the treatment of the Beneficiary's newly discovered glioblastoma and Medicare coverage requirements have been met for the dates of service at issue.

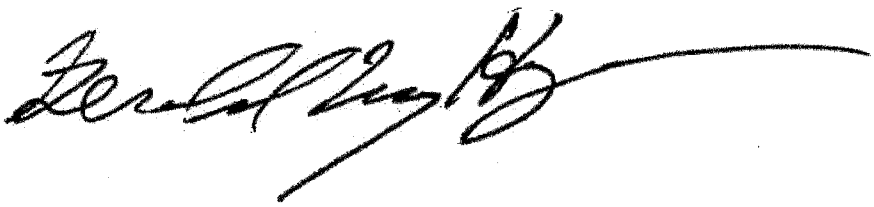
CONCLUSIONS OF LAW

Medicare coverage does exist for the Tumor Treatment Field Therapy (E0766) received by the Beneficiary/Appellant on November 9, 2018; December 9, 2018; January 9, 2019; February 9, 2019; March 9, 2019; April 9, 2019; and May 9, 2019, from Novocure Inc., and the Beneficiary/Appellant is entitled to payment for the same.

Order

For the reasons discussed above, this decision is **FULLY FAVORABLE.** I direct the Medicare contractor to process the claim in accordance with this decision.

SO ORDERED



Gerald Hynum
Administrative Law Judge

DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, and any other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 9.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment of representative if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, FL

Appeal of: **R. LEWIS JR**	OMHA Appeal No.: **3-8693279102**
Beneficiary: **R. LEWIS JR**	Medicare Part: **B**
Medicare No.: *******1077A**	Before: **Gerald Hynum** Administrative Law Judge

Index of the Administrative Record and Exhibit List

Exhibit Record	**Administrative File Reference** File Name	Page Range
All Documents: Procedural Documents	3-8693279102 00001	1 : 15
All Documents: Procedural Documents	3-8693279102 00003	1 : 34
All Documents: Procedural Documents	3-8693279102 00004	1 : 14
All Documents: Request for Hearing	3-8693279102 00005	1 : 5

Exhibit Record	**Administrative File Reference** File Name	Page Range
Position Statements: General: Procedural -LCD Info	3-8693279102 00002	1 : 3402

EXHIBIT G

19-101

RECEIVED JUN 05 2019

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington Field Office
2550 South Clark Street, Suite 3001
Arlington, VA 22202
571-457-7200 (Main)
571-457-7276 (ALJ Levine Team)
703-603-1812 (Fax)
866-231-3087 (Toll Free)

Date: MAY 30 2019

R. LEWIS JR
1620 TURK RD
WARRINGTON, PA 18976-1113

NOTICE OF DECISION

Appellant: R. LEWIS JR
OMHA Appeal Number: 1-8411344383

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 calendar days from the date of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's Medicare number (Health Insurance Claim Number or Medicare Beneficiary Identifier);
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's decision;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed decision to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review within 60 calendar days after receipt of this notice of

decision. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file.

Please note that your request for review will only be expedited if (1) the appeal involves an issue specified in 42 C.F.R. § 423.566(b), but does not include solely a request for payment of a Part D drug that has already been furnished, and (2) the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

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Enclosures:

OMHA-152, Decision
DAB-101, Request for Review

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington Field Office
Arlington, Virginia

Appeal of:	**R. Lewis Jr.**	ALJ Appeal No.:	**1-8411344383**
Beneficiary:	**R. Lewis Jr.**	Medicare:	**Part B**
HICN:	*****1077A**	Before:	**Pamela Levine** Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record and at the hearing, an **UNFAVORABLE** decision is entered against R. Lewis ("Appellant"/"Beneficiary").

PROCEDURAL HISTORY

Novocure, Inc. ("Provider") submitted a claim for reimbursement of an Optune system, a type of Tumor Treatment Field Therapy ("TTFT") electric stimulation device used for cancer treatment ("Elec Stim Cancer Treatment") (HCPCS Code E0766), provided to the Beneficiary on July 9, 2018, August 9, 2018, September 9, 2018, and October 9, 2018. (Exh. 1, pp. 3, 35-38). The Medicare Appeals Contractor ("Contractor") denied payment for the services initially and on redetermination. (*Id.* at 23-25). The Beneficiary requested reconsideration from the Qualified Independent Contractor ("QIC"). On March 19, 2019 the QIC upheld the denial stating that the TTFT was denied as not reasonable and necessary under the applicable Local Coverage Determination ("LCD"), and the Provider was liable for the non-covered services. (*Id.* at 1-11).

On March 27, 2019, the Office of Medicare Hearings and Appeals ("OMHA") received the Beneficiary's timely filed request for a hearing before an Administrative Law Judge ("ALJ") filed by the Beneficiary's appointed representative, Debra M. Parrish, Esq. (Exh. 3, pp. 1-4). The amount in controversy meets the jurisdictional requirements for an ALJ appeal decision. 42 C.F.R. §405.1006.

I held a telephone hearing on May 9, 2019. Ms. Parrish appeared on behalf of the Beneficiary and provided argument. (Hearing CD). Mr. Tim Parks, Registered Nurse and Provider representative, presented as a witness for the Beneficiary and provided sworn testimony. (*Id.*). Exhibits 1 through 4 were admitted without objection. The administrative record is now closed.

ISSUES

1. Whether the TTFT/Elec Stim Cancer Treatment (HCPCS Code E0766) provided to the Beneficiary on July 9, 2018, August 9, 2018, September 9, 2018, and October 9, 2018 met Medicare coverage criteria.

2. Whether the services are medically necessary in accordance with §1862(a)(1)(A) of the Social Security Act ("the Act"), and are reimbursable under Medicare.

3. If reimbursement for the services is denied, whether Medicare payment for the non-covered services may nevertheless be made under the limitation of liability provisions of §1879 of the Act.

FINDINGS OF FACT

1. The Beneficiary, a 68-year-old male, underwent left frontal craniotomy on February 27, 2018 due to left temporal brain mass, which revealed glioblastoma multiforme ("GBM"). (Exh. 2, pp. 3-9). Chemo-radiation was complete on May 16, 2018; and the Beneficiary was subsequently started on adjuvant Temozolomide. (*Id.* at 1, 9). The radiation oncologist recommended the Beneficiary commence TTFT "as an open-label randomized trial recently suggested that the device may improve both progression-free and overall survival when used along with temozolomide in patients with newly diagnosed glioblastoma in the post-radiation setting." (*Id.* at 9). A radiology exam summary dated June 19, 2018 indicates an MRI performed that day revealed expected interval evolution of post-surgical changes and no suspicious enhancement or evidence of progressive neoplasm. (*Id.* at 1-2).

2. On June 22, 2018, the Beneficiary's radiation oncologist signed a prescription for six months' use of Optune for treatment of the Beneficiary's GBM. (Exh. 2, pp. 11-15).

3. An Optune Service Agreement was signed by the Beneficiary on July 9, 2018 indicating the Beneficiary agreed to participate in a treatment education session conducted by Provider personnel. (Exh. 2, pp. 16-30).

4. There are no Beneficiary medical records included in the file that are dated after the Beneficiary commenced utilizing the TTFT. (Exh. 2).

5. On August 7, 2018, a letter from CMS responded to the Provider's reconsideration request of the TTFT LCD coverage criteria. (Exh. 1, pp. 20-22). CMS's letter notes the LCD currently includes language indicating that coverage of TTFT for recurrent GBM is not reasonable and necessary; however, coverage of newly diagnosed GBM is not addressed; and the Provider's request asks the LCD to (1) allow coverage for recurrent GBM and (2) add coverage for newly diagnosed GBM. (*Id.*). CMS's letter indicates that only the Provider's request to add coverage for newly diagnosed GBM was valid; and CMS would provide a final decision on that request by September 18, 2018. (*Id.*).

LEGAL FRAMEWORK

I. ALJ Review Authority

A. Jurisdiction, Scope of Review, and Standard of Review

An individual who is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before an ALJ provided there is a sufficient amount in controversy and the individual timely requests a hearing. Act §§205(b), 1869(b)(1)(A), (d)(1); *see also* 42 C.F.R. §§405.924(b), 405.1000(a), 405.1002(a), 405.1014.

The issues before an ALJ include all issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in an appellant's favor. 42 C.F.R. §405.1032(a). An ALJ conducts a *de novo* review and issues a decision based on the administrative record, including the hearing record. 42 C.F.R. §405.1000(d).

Appellant has the burden of proving each element of a Medicare claim by a preponderance of the evidence. *See* Act §1833(e); 42 C.F.R. §§405.1018, 405.1028, 405.1030, and 424.5(a)(6).

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Title XVIII of the Act, is administered through the Centers for Medicare and Medicaid Services ("CMS"), a component of HHS. Under the authority of §1842(a)(1)(A) of the Act, the Secretary is authorized to enter into contracts with private entities for the day-to-day operations of the program.

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. Section 1861(s)(1) of the Act defines the term "medical and other health services" and specifically includes physicians' services. *See also* 42 CFR §410.10(a).

Section 1833(e) of the Act states that "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period."

Coverage of medical and other health services is qualified by the overarching principles of the Act, §1862(a), which provides that Medicare payments will only be made for items or services that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," notwithstanding any other provision of Title XVIII of the Act. *See also* 42 C.F.R. § 411.15(k)(1).

If it is determined that Medicare cannot pay for the services at issue, §1879 of the Act may assign liability for the payment of these services. If the beneficiary had no knowledge that the

services would not be covered, but the provider of the services did, then the provider is liable and cannot seek or retain payment by the beneficiary. The regulations at 42 C.F.R. §411.400 *et seq.* and HCFA Ruling 95-1 address how to determine if the beneficiary or provider/supplier had the requisite degree of knowledge to make them liable under §1879 of the Act. In general, the existence of a notice, manual, or community medical standard is sufficient to constitute notice as applicable to the provider. *See also*, 42 C.F.R. §411.406.

B. National Coverage Determinations

A National Coverage Determination ("NCD"), if applicable, is binding on the ALJ. 42 C.F.R. §405.1060(a)(4). There is no applicable NCD in this case.

C. Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local medical review policies ("LMRPs") or local coverage determinations ("LCDs"). CGS Admins., LLC, Local Coverage Determination L34823: Tumor Treatment Field Therapy (TTFT) (LCD L34823) (Jan. 2017) and CGS Admins., LLC, Article A52711: Tumor Treatment Field Therapy (TTFT) (Article A52711) (Jan. 2017) apply in this case.

ANALYSIS

The Beneficiary is seeking coverage for TTFT/Elec Stim Cancer Treatment (HCPCS Code E0766) provided to him on July 9, 2018, August 9, 2018, September 9, 2018, and October 9, 2018. (Exh. 1, p. 3; Exh 3, p. 1).[1] The QIC upheld the denial, stating that TTFT was not reasonable and necessary under the applicable LCD and the Provider was liable for the non-covered services. (Exh. 1, pp. 1-11).

At the hearing, and in written argument submitted to OMHA, the Beneficiary's representative, Ms. Parrish, argued that no basis exists to deny Medicare coverage of the TTFT device that has shown to be safe and effective treatment for GBM. (Exh. 3, pp. 1-3; Hearing Audio). Ms. Parrish stated that Optune is FDA-approved for recurrent and newly diagnosed GBM brain tumors. (*Id.*). She indicated that peer-reviewed literature further supports the safety and efficacy of the Optune system and TTFT generally. (*Id.*). She noted that these studies are reported in prestigious journals such as the *Journal of American Medical Association*. (*Id.*). She also pointed out that Optune is included in the National Comprehensive Cancer Network guidelines for recurrent GBM and for newly diagnosed GBM in combination with temozolomide. (*Id.*). She contended

[1] Although the Beneficiary received a prescription on June 22, 2018 for Optune services for six months, the issue in this case is whether the Provider is entitled to payment from Medicare for the services provided to the Beneficiary on July 9, 2018, August 9, 2018, September 9, 2018, and October 9, 2018 only. (Exh. 1, p. 3; Exh. 2, pp. 11-15; Exh. 3, p. 1).

that Optune has improved the clinical outcome of patients who use the device. (*Id.*). With respect to the limited number of clinical trials conducted, she argued that the treatment is so effective that the last U.S. clinical trial was stopped early, and it would be unethical to conduct additional clinical trials which involve withholding a proven effective treatment for a fatal disease. (*Id.*).

At the hearing, Mr. Parks testified that the Beneficiary began using the device in July 9, 2018, the first date of service at issue in this appeal, and the Beneficiary continues to use it to this day. (*Id.*). He stated that there has been no progression in the Beneficiary's disease since the Beneficiary began use of the device. (*Id.*).

Despite the above-mentioned support for the effectiveness and adoption of the TTFT device however, Medicare guidelines are clear that TTFT is not covered. A basis for denial certainly exists in that the applicable LCD L34823 entitled "LCD of Tumor Treatment Field Therapy (TTFT)" (effective Jan. 1, 2017) states, in relevant part, "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary." LCD L34823. The related Policy Article A52711, entitled "Article for Tumor Treatment Field Therapy (TTFT)" (effective Jan. 1, 2017) states the following:

> Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act § 18 62 (a) (1) (A)). In order for a beneficiary's equipment to be eligible for reimbursement *the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met.*

Policy Article A52711 (emphasis added). There is no dispute that the HCPCS code for the TTFT device at issue is E0766. Because TTFT is categorized by the LCD as not reasonable and necessary, payment for it cannot be made under the durable medical equipment benefit under Section 1861(n) of the Social Security Act.

Moreover, although the Beneficiary's representative contends that Optune has improved the clinical outcome of patients who use the device, it is impossible to consider whether the Beneficiary is responding well to treatment because there are no Beneficiary medical records included in the file that are dated after he commenced utilizing the TTFT. (Exh. 2). Thus, even if the TTFT was generally covered by Medicare, there is insufficient medical evidence in the record to support payment for the treatment in this case. (*Id.*)

Ms. Parrish, orally and in writing, also raised the argument that the applicable LCD on its face does not reflect the current peer-reviewed literature, consensus of experts, and adoption. (Exh. 3, pp. 1-3; Hearing Audio). Indeed, LCD L34823 currently is the subject of a reconsideration request submitted by the Provider to CMS. (Exh. 1, pp. 20-22; Hearing Audio). On August 7, 2018, CMS responded to the Provider's reconsideration request of the TTFT LCD coverage criteria. (*Id.*). CMS's letter notes the LCD currently includes language indicating that coverage of TTFT for recurrent GBM is not reasonable and necessary; however, coverage of newly diagnosed GBM is not addressed; and the Provider's request asks the LCD to (1) allow coverage for recurrent GBM and (2) add coverage for newly diagnosed GBM. (*Id.*) CMS's letter indicates that only the Provider's request to add coverage for newly diagnosed GBM was valid; and CMS would provide a final decision on that request by September 18, 2018. (*Id.*) At the hearing, the Provider's representative testified that, to date, the Provider has not received a final decision

from CMS. (Hearing Audio). However, Ms. Parrish and the Provider representative contended that the Contractor has indicated the LCD does not apply to newly diagnosed GBM patients, as is the case with this Beneficiary, and thus it should not be used to preclude coverage in this case. (Exh. 3, pp. 1-3; Hearing Audio).

The Provider appropriately challenged the reasonableness of the LCD through the above-mentioned, separate reconsideration appeal, however, concerns that an LCD is not supported by the medical community or medical research are not a basis for an ALJ to decline application of a relevant LCD. Although not bound by LCDs, Medicare regulations require ALJs and the Medicare Appeals Council ("MAC") to "give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. §405.1062(a). The ALJ or MAC must explain the reasons why the policy was not followed, and any deviation from the LCD does not have precedential effect. 42 C.F.R. §405.1062(b). However, the ALJ or MAC "may not set aside or review the validity of [an LCD] for purposes of a claim appeal." 42 C.F.R. §405.1062(c). Specifically with respect to tumor treatment field therapy, the MAC has made it clear that, "we cannot question the validity of a contractor's LCD or substitute our own judgment on review of the medical research for the medical judgment of the contractor which determined categorically that the device is not reasonable and necessary." *See In re BlueCross BlueShield of North Carolina,* MAC (Jan. 2016) (M-15-1354) (reversing an ALJ decision to decline to follow LCD L34823).

Importantly, the judgment of the Beneficiary's physicians and potential benefit of the treatment is not at issue. 42 C.F.R. §405.1062 requires that substantial deference be given to the applicable LCD unless there is a reason particular to a specific case that supports deviation from the Contractor's judgment. Moreover, the MAC has made clear that cases involving coverage determinations are not the proper forum for inquiries into the reasonableness of an LCD. *In Re BlueCross BlueShield of North Carolina*, MAC (Jan. 2016). The LCD, as it stands currently, is quite specific and is still currently in effect. The LCD is clear that coverage of TTFT for recurrent GBM is not reasonable or necessary. As to the reasonableness or necessity of coverage of TTFT for newly diagnosed GBM, the LCD is silent. The undersigned cannot read into the LCD's silence what the Beneficiary would like it to say or what the LCD may say in the future.

Post-hearing, on May 10, 2019, DME Contractors issued a proposed LCD DL3423: Tumor Treatment Field Therapy (TTFT) (LCD DL3423) to source LCD L34823 for narrow coverage of GBM treatment; the proposed LCD is subject to public comment through June 24, 2019.[2] The proposed LCD provides guidance on initial coverage for newly diagnosed GBM when certain criteria are met; and continued coverage for newly diagnosed GBM beyond the first three months of therapy, when additional criteria are met. As a preliminary matter, the proposed LCD is not in yet in effect and I am not obliged to consider criteria as described in proposed policy guidance. Nevertheless, even if the proposed LCD were applicable as it stands today, the Beneficiary's request for coverage in this case would remain denied because the criteria for coverage for newly diagnosed GBM has not been met in this case. In relevant part, the proposed LCD DL34823 provides that TTFT is only covered for the treatment of newly diagnosed GBM when all of the following criteria are met:

[2] *See*, CGS Admins., LLC, *Tumor Treatment Field Therapy (TTFT) (DL34823) Proposed LCD Released for Comment*: https://www.cgsmedicare.com/jc/pubs/news/2019/05/cope12405.html.

1. The beneficiary has histologically confirmed (World Health Organization (WHO) grade IV astrocytoma), newly diagnosed, supratentorial GBM; and,

2. The beneficiary has received initial treatment with maximal debulking surgery, followed by chemotherapy and radiotherapy; and,

3. Tumor treatment field therapy is initiated within 7 weeks from the last dose of concomitant chemotherapy or radiotherapy; and,

4. The beneficiary is receiving care for GBM at a National Cancer Institute-designated Cancer Center, National Cancer Institute-designated Comprehensive Cancer Center, or National Cancer Institute-designated Cancer Research Network facility; and,

5. The beneficiary has no evidence of progression by Response Assessment in Neuro-Oncology (RANO) criteria; and,

6. The beneficiary has a Karnofsky Performance Score (KPS) of at least 70; and,

7. The beneficiary will use TTFT for at least 18 hours/day.

The record confirms the Beneficiary was diagnosed with GBM, received debulking surgery, and completed chemo-radiation on May 16, 2018. (Exh. 2, pp. 1, 3-9). However, the Beneficiary did not begin to use TTFT until July 9, 2018; therefore, TTFT was not initiated within seven weeks from the last dose of concomitant chemotherapy or radiotherapy, as required by the proposed LCD DL34823. Moreover, as mentioned above, there are no Beneficiary medical records included in the file that are dated after the Beneficiary commenced utilizing the TTFT. (Exh. 2). Therefore, it is impossible to determine whether there is evidence of progression by RANO criteria. (*Id.*). Finally, there is no KPS of at least 70 documented in the record. (*Id.*). Thus, here, requirements for the narrow coverage of GBM treatment proposed in this draft LCD are not met.

Based on the foregoing considerations, the TTFT/Elec Stim Cancer Treatment (HCPCS Code E0766) provided to the Beneficiary on July 9, 2018, August 9, 2018, September 9, 2018, and October 9, 2018 are not eligible for payment because the services failed to satisfy the conditions for Medicare payment.

LIMITATION ON LIABILITY

The file did not contain an Advance Beneficiary Notice or any other form of notice. The Beneficiary neither knew, nor reasonably should have been expected to know, that any of the services would not be covered by Medicare. The liability of the Beneficiary is waived.

However, the Provider, is presumed to have known the requirements for submitted claims. 42 C.F.R. §411.406(e). The record contains no evidence to rebut the presumption that the Provider knew, or should have known, the services were not covered under the Medicare program. Therefore, the Provider is liable for the non-covered charges pursuant to §1879.

CONCLUSIONS OF LAW

The TTFT/Elec Stim Cancer Treatment (HCPCS Code E0766) provided to the Beneficiary on July 9, 2018, August 9, 2018, September 9, 2018, and October 9, 2018 failed to meet Medicare coverage requirements. Novocure, the Provider, is liable for the non-covered services.

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: MAY 30 2019

Pamela Levine

Pamela Levine
Administrative Law Judge

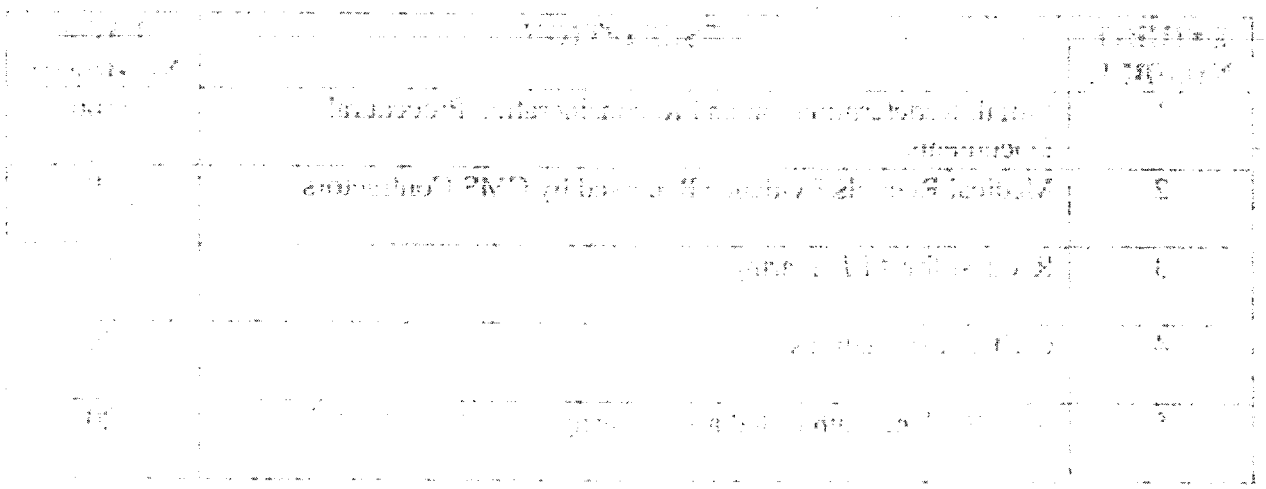
Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia

Appeal of:	**R. LEWIS JR**	OMHA Appeal No.:	**1-8411344383**
Beneficiary:	**R. LEWIS JR**	Medicare:	**Part B**
Medicare No.:	*******1077A**	Before:	**Pamela Levine** **Administrative Law Judge**

EXHIBIT LIST

EXHIBIT NUMBER	DESCRIPTION	PAGE NUMBERS
1	Initial, Redetermination and Reconsideration Procedural Documents	1806
2	Medical Records/Evidence Received by CMS Contractors	30
3	Request for ALJ Hearing	15
4	OMHA Proceedings	30
5	New Evidence submitted after hearing	20

Dated: May 30, 2019



DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) / DEPARTMENTAL APPEALS BOARD Form DAB-101 (08/09)

REQUEST FOR REVIEW OF ADMINISTRATIVE LAW JUDGE (ALJ) MEDICARE DECISION / DISMISSAL

1. APPELLANT (the party requesting review)	2. ALJ APPEAL NUMBER (on the decision or dismissal)
3. BENEFICIARY*	4. HEALTH INSURANCE CLAIM NUMBER (HICN)*

*If the request involves multiple claims or multiple beneficiaries, attach a list of beneficiaries, HICNs, or other information to identify all claims being appealed.

5. PROVIDER, PRACTITIONER, OR SUPPLIER	6. SPECIFIC ITEM(S) OR SERVICE(S)

7. Medicare claim type: ☐ Part A ☐ Part B ☐ Part C - Medicare Advantage
☐ Part D - Medicare Prescription Drug Plan ☐ Entitlement/enrollment for Part A or Part B

8. Does this request involve authorization for an item or service that has not yet been furnished?
☐ Yes If Yes, skip to Block 8.
☐ No If No, Specific Dates of Service:

9. If the request involves authorization for a prescription drug under Medicare Part D, would application of the standard appellate timeframe seriously jeopardize the beneficiary's life, health, or ability to regain maximum function (as documented by a physician) such that expedited review is appropriate? ☐ Yes ☐ No

I request that the Medicare Appeals Council review the ALJ's ☐ decision or ☐ dismissal order [check one] dated _____. I disagree with the ALJ's action because (specify the parts of the ALJ's decision or dismissal you disagree with and why you think the ALJ was wrong):

(Attach additional sheets if you need more space)

PLEASE ATTACH A COPY OF THE ALJ DECISION OR DISMISSAL ORDER YOU ARE APPEALING.

DATE			DATE		
APPELLANT'S SIGNATURE (the party requesting review)			REPRESENTATIVE'S SIGNATURE (include signed appointment if not already submitted.)		
PRINT NAME			PRINT NAME		
ADDRESS			ADDRESS		
CITY, STATE, ZIP CODE			CITY, STATE, ZIP CODE		
TELEPHONE NUMBER	FAX NUMBER	E-MAIL	TELEPHONE NUMBER	FAX NUMBER	E-MAIL

(SEE FURTHER INSTRUCTIONS ON PAGE 2)

If you have additional evidence, submit it with this request for review. If you need more time, you must request an extension of time in writing now, explaining why you are unable to submit the evidence or legal argument now.

If you are a provider, supplier, or a beneficiary represented by a provider or supplier, and your case was reconsidered by a Qualified Independent Contractor (QIC), the Medicare Appeals Council will not consider new evidence related to issues the QIC has already considered unless you show that you have a good reason for submitting it for the first time to the Medicare Appeals Council.

IMPORTANT: Include the HICN and ALJ Appeal Number on any letter or other material you submit.

This request must be received within 60 calendar days after you receive the ALJ's decision or dismissal, unless we extend the time limit for good cause. We assume you received the decision or dismissal 5 calendar days after it was issued, unless you show you received it later. If this request will not be received within 65 calendar days from the date on the decision or dismissal order, please explain why on a separate sheet.

You must file your request for review in writing with the Medicare Appeals Council at:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

You may send the request for review by U.S. Mail, a common carrier such as FedEx, or by fax to (202) 565-0227. If you send a fax, please do not also mail a copy. ***You must send a copy of your appeal to the other parties and indicate that all parties, to include all beneficiaries, have been copied on the request for review. For claims involving multiple beneficiaries, you may submit a copy of the cover letters issued or a spreadsheet of the beneficiaries and addresses who received a copy of the request for review.***

If you have any questions about your request for review or wish to request expedited review of a claim involving authorization of your prescription drug under Medicare Part D, you may call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100. You may also visit our web site at www.hhs.gov/dab for additional information on how to file your request for review.

PRIVACY ACT STATEMENT

The collection of information on this form is authorized by the Social Security Act (section 205(a) of title II, section 702 of title VII, section 1155 of Title XI, and sections 1852(g)(5), 1869(b)(1), 1871, 1872, and 1876(c)(5)(B) of title XVIII, as appropriate). The information provided will be used to further document your claim. Information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your claim. Information you furnish on this form may be disclosed by the Department of Health and Human Services or the Social Security Administration to another person or governmental agency only with respect to programs under the Social Security Act and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services, the Social Security Administration, or other agencies.

EXHIBIT H

Docket Number: M-19-2164

Appeal Information

Appellant name

RONALD LEWIS, JR.

Appellant type

BENEFICIARY

Appellant representative

DEBRA M. PARRISH

ALJ appeal number

1-8411344383

ALJ decision date

05/30/2019

Medicare contractor

Claim type

Part B

Service type

DME items

Case involving an overpayment?

No

Overpayment

Amount in controversy

$84,000

Date or period of service start

07/09/2018

Date or period of service end

10/09/2018

#	Document Name	Uploaded By	Date Uploaded
1	**dab101.pdf** [223 KB] Request for Review (Form DAB-101)	Tanya Terza	07/05/2019 12:20 pm
2	**AOR_signed.pdf** [104 KB] Appointment of Representative (Form CMS-1696)	Tanya Terza	07/05/2019 12:20 pm
3	**ALJ_Decision_19-101_(Lewis)_Unfavorable_5.30....** [1 MB] Copy of ALJ Decision/Dismissal Order	Tanya Terza	07/05/2019 12:20 pm

#	Document Name	Uploaded By	Date Uploaded
4	**MAC_appeal_19-101_(Lewis)_E-FILED_7-5-19.pdf** [2 MB] Memorandum or brief or other written statement in support of your appeal	Tanya Terza	07/05/2019 12:20 pm
5	**Escalation_Request_12-31-19_(Lewis).pdf** [584 KB] Other	Tanya Terza	12/31/2019 11:31 am

HHS Headquarters

U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Toll Free Call Center: 1-877-696-6775

PARRISH LAW OFFICES

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412.561.6250
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E-mail: info@dparrishlaw.com

December 31, 2019

VIA E-file
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, DC 20201

RE: Request for Escalation
Appellant/Medicare Beneficiary: Ronald C. Lewis, Jr.
HICN: 4R36U76UU87
ALJ Decision Date: May 30, 2019
ALJ Appeal No.: 1-8411344383
Council No.: M-19-2164 (filed July 5, 2019)
Our Ref: 19-101

Dear Medicare Appeals Council:

Mr. Lewis has received a favorable ALJ decision finding TTFT meets Medicare coverage criteria for him. See ALJ No. 3-8693279102. The Secretary chose not to appeal the decision and it has become final. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues with respect to Mr. Lewis. As noted by a unanimous Supreme Court, "We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality." *See Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). The application of issue preclusion would not work as basic unfairness against the Secretary and there are no special circumstances that would make it unfair to apply the doctrine.

The above-captioned Medicare beneficiary appeal has been pending for more than 90 days. Accordingly, pursuant to 42 C.F.R. §405.1132, Mr. Lewis requests escalation of the above-captioned claims to District Court.

Sincerely,

Debra M. Parrish for
Medicare Beneficiary Ronald Lewis, Jr.

Enclosure: Final ALJ Decision
cc: Ronald Lewis, Jr.
Novocure
C2C

Department of Health and Human Services
Office of the Secretary

OFFICE OF MEDICARE HEARINGS AND APPEALS

Miami Field Office
51 SW 1st Avenue
Suite 1536
Miami, FL 33130-1608
(786) 792-3700
(786) 792-3810 (Direct)
(305) 755-9135 (Fax)
(866) 622-0382 (Toll Free)

October 24, 2019

PARRISH LAW OFFICES
ATTN: DEBRA PARRISH
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

NOTICE OF DECISION

Appellant: R. LEWIS JR
OMHA Appeal Number: 3-8693279102

Enclosed is the decision for the above case. This decision is based on the administrative record, including any evidence or testimony presented at the hearing, if one was held. The decision is not precedential, does not release the appellant from civil or criminal liability, and may be reopened at any time if it was procured by fraud or similar fault. In addition, the decision may be reopened within 180 days of the decision for good cause. Good cause exists when there is new and material evidence that was not available or known at the time of the decision and may result in a different conclusion, or when the evidence that was considered clearly shows on its face that an obvious error was made at the time of the decision.

What if I disagree with the decision?

If you disagree with the decision, you may file an appeal with the Medicare Appeals Council. Other parties may also appeal the decision. In addition, the Medicare Appeals Council may decide to review the decision on its own motion. If no party appeals the decision and the Medicare Appeals Council does not review the decision, the decision is binding on all parties and you and the other parties will not have the right to ask a federal court to review the decision.

If you are not already represented, you may appoint an attorney or other person to represent you.

How much time do I have to file an appeal?

The Medicare Appeals Council must receive your written appeal **within 60 calendar days** of the date that you receive this notice. The Medicare Appeals Council assumes you received this notice 5 calendar days after the date of the notice unless you show that you did not receive it within the 5-day period.

The Medicare Appeals Council will dismiss a late request for review unless you show that you had a good reason for not filing it on time.

How do I file an appeal?

To appeal, you must ask the Medicare Appeals Council to review the decision. Your appeal must be in writing, except that a request for expedited review of a Part D decision may be made orally as described below. Your appeal must identify the parts of the decision that you disagree with, and explain why you disagree.

You may submit a written request for review to the Medicare Appeals Council using one of three available methods: mail, fax, or electronic filing (E-File). **Please do not submit your request for review using more than one method**. Regardless of how you file your appeal, **you must always send a copy of your written request for review to the other parties who received a copy of the decision.**

If you are filing a written request for review, you may use the enclosed *Request for Review* (Form DAB-101), or you may write a letter containing the following:

- The beneficiary's/enrollee's name (and telephone number for Part D appeals);
- The beneficiary's/enrollee's health insurance claim number;
- The item(s), service(s), or specific Part D drug(s) in dispute;
- The specific date(s) the item(s) or service(s) were provided, if applicable;
- For Part D appeals, the plan name;
- For Part D appeals, the OMHA Appeal Number on the adjudicator's dismissal;
- For Part D appeals requesting expedited review, a statement that you are requesting expedited review;
- The date of the adjudicator's decision (not required for Part D appeals); and
- Your name and signature, and, if applicable, the name and signature of your representative.

Filing by mail:

Mail your appeal and a copy of the enclosed decision to:

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Filing by fax:

Fax your appeal and a copy of the enclosed dismissal to **(202) 565-0227.**

Filing by computer:

Using your web browser, visit the Medicare Operations Division Electronic Filing System (MOD E-File) website at **https://dab.efile.hhs.gov/mod**.

To file a new appeal using MOD E-File, you will need to register by:

(1) Clicking **Register** on the MOD E-File home page;
(2) Entering the information requested on the "Register New Account" form; and
(3) Clicking **Register Account** at the bottom of the form.

You will use the email address and password you provided during registration to access MOD E-File at **https://dab.efile.hhs.gov/mod/users/new**. You will be able to use MOD E-File to file and access the specific materials for appeals to which you are a party or a party's representative. You may check the status of any appeal on the website homepage without registering.

Once registered, you may file your appeal by:

(1) Logging into MOD E-File;
(2) Clicking the **File New Appeal** menu button on the top right of the screen;
(3) Selecting the type of appeal you are filing (Request for Review or Request for Escalation); and
(4) Entering the requested Appeal Information and uploading the requested Appeal Documents on the "File New Appeal – Medicare Operations Division" form. You are required to provide information and documents marked with an asterisk.

At a minimum, the Medicare Appeals Council requires an appellant to file a signed Request for Review and a copy of the enclosed decision. All documents should be submitted in Portable Document Format (PDF) whenever possible. Any document, including a Request for Review, will be deemed to have been filed on a given day, if it is uploaded to MOD E-File on or before 11:59 p.m. EST of that day.

Currently, the documents that may be filed electronically are the:

(1) Request for Review;
(2) Appointment of Representative form (OMB Form 0938-0950);
(3) Copy of Administrative Law Judge or attorney adjudicator decision;
(4) Memorandum or brief or other written statement in support of your appeal; and
(5) Request to Withdraw your appeal

No other documents aside from the five (5) listed categories above may be submitted through MOD E-File.

Filing by oral request (for expedited review only):

Oral requests for expedited review of a Part D decision may be made by telephone to **(866) 365-8204.** You must provide the information listed in the bullet points above and a statement that you are requesting an expedited review. The Medicare Appeals Council will document the oral request in writing and maintain the documentation in the case file. Please note that your request for review will only be expedited if the Part D drug has not already been furnished and the prescribing physician (or other prescriber) indicates, or the Medicare Appeals Council determines, that the standard time frame may seriously jeopardize your life, health, or ability to regain maximum function.

How will the Medicare Appeals Council respond to my appeal?

The Medicare Appeals Council will limit its review to the issues raised in the appeal, unless the appeal is filed by an unrepresented beneficiary/enrollee. It may change the parts of the decision that you agree with. It may adopt, modify, or reverse the decision, in whole or in part, or it may send the case back to OMHA for further action. It may also dismiss your appeal.

Questions?

You may call or write our office. A toll-free phone number and mailing address are at the top of this notice.

Additional information about filing an appeal with the Medicare Appeals Council is available at http://www.hhs.gov/dab/. You can also call the Medicare Appeals Council's staff in the Medicare Operations Division of the Departmental Appeals Board at (202) 565-0100 or (866) 365-8204 (toll free), if you have questions about filing an appeal.

cc:

C2C Innovative Solutions, Inc.
Part B DME C2C
P.O. Box 44006
Jacksonville, FL 32231-4006

DEBRA PARRISH
788 WASHINGTON ROAD
PITTSBURGH, PA 15228

Enclosures:

OMHA-152, Decision

DAB-101, Request for Review

OMHA-156, Exhibit List

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Miami, FL

Appeal of:	**R. LEWIS JR**	OMHA Appeal No.:	**3-8693279102**
Beneficiary:	**R. LEWIS JR**	Medicare Part:	B
Medicare No.:	*******1077A**	Before:	**Gerald Hynum** Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, I enter a **FULLY FAVORABLE** on-the-record decision. The tumor treatment field therapy ("TTFT") provided to the Appellant from November 9, 2018, to May 9, 2019, is covered.

PROCEDURAL HISTORY

The Beneficiary/Appellant, R. Lewis, received Tumor Treatment Field Therapy ("TTFT") (E0766) from the Supplier, Novocure, Inc., from November 9, 2018, to May 9, 2019. The Appellant's claim to Medicare was denied by Noridian Healthcare Solutions, a Medicare Administrative Contractor ("Contractor"), upon initial and redetermination. On August 7, 2019, C2C Innovative Solutions, a Medicare Qualified Independent Contractor ("QIC"), upheld the prior denials upon reconsideration review. By correspondence received August 22, 2019, the Appellant made a request for an Administrative Law Judge ("ALJ") hearing before the Office of Medicare Hearings and Appeals ("OMHA").

Exhibits 1 through 5 were admitted into the record without objection. This decision is being issued in the absence of a hearing as careful consideration of all the documents identified in the record has resulted in a decision fully favorable to the Appellant. 42 C.F.R. § 405.1038(a).

ISSUES

Whether the Tumor Treatment Field Therapy ("TTFT") (E0766) received by the Appellant from the Supplier, Novocure, Inc., from November 9, 2018, to May 9, 2019, may be covered under Medicare Part B, and, if not, who is liable for the non-covered charges?

PRINCIPLES OF LAW

Unless the ALJ dismisses the hearing, the ALJ will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. 42 C.F.R. § 405.1046(a). The decision must be based on evidence offered at the hearing or otherwise admitted into the record. *Id.*

Medicare Part B provides coverage to eligible beneficiaries for all or part of the cost of "medical and other health services," a term which is defined by the Act to include durable medical equipment. Act §§ 1832(a)(1)(B) and 1861(s)(6); 42 C.F.R. §410.10(h). No Medicare payment can be allowed for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Act § 1862(a)(1)(A); 42 C.F.R. §411.15(k)(2).

Policy and Guidance

Section 1871(a)(2) of the Act states that unless promulgated as a regulation by CMS, no rule, requirement, or statement of policy, other than National Coverage Determinations, can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program. *See also* 42 CFR §405.860. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance that describe criteria for coverage of selected types of medical items and services in the form of manuals and local coverage determinations ("LCDs"). Administrative Law Judges are not bound by LCDs or CMS program guidance but must give substantial deference to these policies if they apply to a particular case. 42 C.F.R. § 405.1062(a). When an ALJ declines to follow a policy in a particular case, the ALJ's decision must set forth the reasons for departing from the policy. 42 C.F.R. § 405.1062(b).

FINDINGS OF FACT

After careful consideration of the entire record, a preponderance of the evidence establishes the following facts:

1. The amount in controversy is in excess of $160.00. The QIC issued an unfavorable reconsideration decision on August 7, 2019 (File 1, p. 1). By correspondence received August 22, 2019, the Appellant made a request for an ALJ hearing before OMHA (File 5, p. 1). Exhibits 1 through 5 were admitted into the record without objection.

2. The Beneficiary, a 67-year-old male, was evaluated by his primary care physician after developing word-finding difficulties in early 2018 and a brain CT showed a left temporal brain mass which was confirmed with an MRI obtained in February 2018 (File 3, pp. 16, 19).

3. On February 27, 2018, the Beneficiary underwent surgical resection and pathology demonstrated that he had grade IV glioblastoma (File 3, p. 16). A physician progress note from April 2018 provides that the Beneficiary was in the midst of current chemoradiation with Temodar which he was tolerating well (*Id.*, p. 22). The physician noted that the plan was to obtain another MRI 4 weeks after radiation is finished and proceed with a minimum of 6 cycles of adjuvant temozolomide and tumor treatment field therapy with the Optune device after the Beneficiary completes radiation therapy (*Id.*).

4. The Beneficiary received TTFT on November 9, 2018; December 9, 2018; January 9, 2019; February 9, 2019; March 9, 2019; April 9, 2019; and May 9, 2019 (File 1, p. 13).

ANALYSIS

The amount in controversy is in excess of $160.00. The reconsideration decision was issued on August 7, 2019, and by correspondence received August 22, 2019, the Appellant made

a request for an ALJ hearing before OMHA. Accordingly, the Appellant's request for a review is timely and the claim satisfies the jurisdictional requirements for an ALJ hearing before OMHA. Exhibits 1 through 5 were admitted into the record without objection. This decision is being issued in the absence of a hearing as careful consideration of all the documents identified in the record has resulted in a decision fully favorable to the Appellant. 42 C.F.R. § 405.1038(a).

The Appellant/Beneficiary was newly diagnosed with glioblastoma, a type of brain cancer, and had surgery, chemotherapy and radiation, and on the dates of service at issue also had Tumor Treatment Field Therapy (TTFT). The TTFT was denied by Medicare.

This Administrative Law Judge conducted a de novo review of the evidence to determine whether the Appellant established the requirements for Medicare coverage. The Appellant's request for an ALJ hearing was timely and satisfied jurisdictional requirements. In this case, this ALJ finds and concludes that the tumor treatment field therapy for treatment of this Beneficiary's glioblastoma for the dates of service was medically reasonable and necessary. First, this ALJ notes that there is no National Coverage Determination specific to tumor treatment field therapy. This ALJ, therefore, looks to the relevant LCD for guidance. ALJs are not bound by LCDs and will give substantial deference to the policies if they are applicable to a particular case. 42 C.F.R. § 405.1062. If an ALJ declines to follow an LCD in a particular case, the ALJ must explain the reasons why the policy was not followed. *Id.* In this case, this ALJ declines to follow LCD L34823 for multiple reasons as further discussed.

In general, this ALJ finds that the therapy has been shown to be safe and effective for use in patients with newly diagnosed glioblastoma (after chemotherapy, radiation and/or surgery has been tried without sufficient success, as is the case here with this Beneficiary) and it is medically reasonable and necessary to treat the Beneficiary's condition. The relevant LCD in effect at the time of the issuance of the QIC's decision states that tumor treatment field therapy will be denied as not reasonable and necessary. The advancement of medicine and science can sometimes outpace the current or relevant version of an LCD. Subsequently, reported data from the FDA, phase III clinical trials and NCCN guidelines are available to this ALJ for review and analysis, and that information shows the LCD may be behind the medical literature curve as applied to this patient. First, this ALJ finds that the Optune device received FDA premarket approval for use in patients with recurrent glioblastoma on April 8, 2011. On October 5, 2015, the FDA gave premarket approval for use of Optune in patients with newly diagnosed glioblastoma. While FDA premarket approval does not establish that the device is medically reasonable and necessary pursuant to Medicare requirements, it does ensure that the FDA has closely examined the device and its application. In this case, the FDA determined that sufficient scientific evidence existed to provide the FDA with assurance that the device was safe and effective for its intended use both in patients with recurrent and newly diagnosed glioblastoma. From this perspective, the use of the device meets Medicare guidance requiring that a device be proven safe and effective based on authoritative evidence, although FDA approval alone is not determinative of Medicare coverage. Medicare does not pay for items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Act § 1 862(a)(1). To be reasonable and necessary, the procedure must be safe and effective and not experimental. The use of TTFT is generally accepted by the medical community. In the 2015 version of the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology Central Nervous System Cancers guidelines, alternating electric field therapy is a treatment option suggested for glioblastoma. This suggestion was found in a treatment guideline from a national cancer organization, not evidence based on an individual physician treating a single patient in a clinical setting. Most commercial health plans now cover TTFT. As such, this ALJ finds that TTFT treatment is generally accepted in the medical

community as safe and effective for the treatment of recurrent glioblastoma based upon the medical literature provided by the Appellant. Although the LCD states that the procedure is not covered, without giving any explanation for the non-coverage, this Judge is not bound by the LCD. *See* 42 C.F.R. 405.1062(a). Based upon the medical evidence this Judge has determined that it is appropriate to depart from the LCD based upon evidence that was not available at the time the LCD was written. Also the applicable LCD has been revised as of September 1, 2019, after the QIC issued its decision in this case, and the revised LCD provides coverage for TTFT treatment of newly discovered glioblastoma. The medical evidence in the record establishes that the Beneficiary had already undergone surgical resection of the tumor and radiation, and the TTFT treatment is the only treatment available to further prolong his life and it has prolonged his life. For all of the reasons stated above, this Judge finds that the Optune (TTFT) system has been shown to be safe and effective, and it was and is medically necessary for the treatment of the Beneficiary's newly discovered glioblastoma and Medicare coverage requirements have been met for the dates of service at issue.

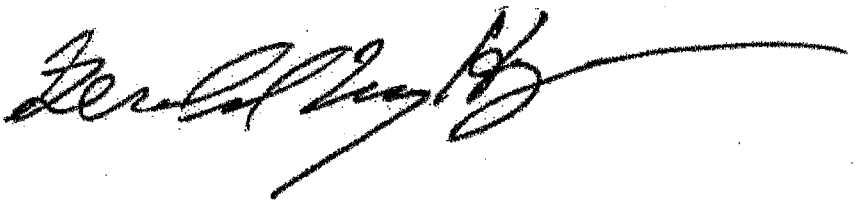
CONCLUSIONS OF LAW

Medicare coverage does exist for the Tumor Treatment Field Therapy (E0766) received by the Beneficiary/Appellant on November 9, 2018; December 9, 2018; January 9, 2019; February 9, 2019; March 9, 2019; April 9, 2019; and May 9, 2019, from Novocure Inc., and the Beneficiary/Appellant is entitled to payment for the same.

Order

For the reasons discussed above, this decision is **FULLY FAVORABLE.** I direct the Medicare contractor to process the claim in accordance with this decision.

SO ORDERED



Gerald Hynum
Administrative Law Judge

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